Exhibit A

EXECUTION VERSION

PORTAL INSTRUMENTS, INC.

AND

LEO PHARMA A/S

COLLABORATION AND LICENSE AGREEMENT

December 3, 2019

TABLE OF CONTENTS

INDEX OF EXHIBITS

COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (the **"Agreement"**) is made and entered into as of the 3rd day of December, 2019 (the **"Effective Date"**), by and between **PORTAL INSTRUMENTS, INC.,** a Delaware corporation with a principal place of business at 190 5th Street, Cambridge, Massachusetts, 02141 (**"Portal"**), and **LEO PHARMA A/S,** a company organized under the laws of the Kingdom of Denmark with a principal place of business at Industriparken 55, DK-2750, Ballerup, Denmark (**"LEO Pharma"**). Portal and LEO Pharma are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**." Except as otherwise provided in Section 19.14 hereof, references to **"Portal"** and **"LEO Pharma"** shall not include their respective Affiliates.

RECITALS

WHEREAS, Portal is a company engaged in the research, development, and commercialization of a novel, computer-controlled, needle-free drug delivery device named "Prime" that is designed to allow large, viscous biological molecules to be rapidly administered to patients;

WHEREAS, LEO Pharma is a pharmaceutical company engaged in the research, development and commercialization of therapeutic drugs useful in the amelioration, treatment and/or prevention of human diseases and conditions;

WHEREAS, LEO Pharma and Portal desire to collaborate in certain activities to develop and gain regulatory approval for certain drugs developed or to be developed by LEO Pharma to be delivered using a version of Portal's proprietary drug delivery device; and

WHEREAS, LEO Pharma desires to obtain, and Portal is willing to grant to LEO Pharma, a license under Portal's proprietary technology to import, develop, commercialize, make, have made, promote, market, use, offer for sale and sell certain products based upon such delivery of such drugs using Portal's proprietary drug delivery device, on the terms and conditions provided in this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the covenants and promises contained in this Agreement and intending to be legally bound, the Parties agree as follows:

1. DEFINITIONS. As used herein, the following terms shall have the following meanings:

1.1 **"1x2mL System"** has the meaning set forth in Section 4.2.

1.2 **"1x2mL System Development Fee"** has the meaning set forth in Section 7.2(a).

1.3 **"1x2mL System Development Period"** has the meaning set forth in Section 7.2(a).

1.4 **"2x1mL System"** has the meaning set forth in Section 4.2.

1.5 **"2x1mL System Development Fee"** has the meaning set forth in Section 7.2(b).

1.6 **"2x1mL System Development Period"** has the meaning set forth in Section 7.2(b).

1.7 **"Acceptance"** means (a) with respect to a BLA or NDA in the United States, the receipt of notice from the FDA that such BLA or NDA has been accepted for filing, and (b) with respect to a submission or filing for Regulatory Approval in any other jurisdiction, any reasonable indicia of acceptance by the relevant Regulatory Authority of such submission or filing.

1.8 **"Accounting Standards"** means GAAP in the case of Portal and IFRS in the case of LEO Pharma.

1.9 **"ACCME Standards"** means the standards set forth by the Accreditation Council for Continuing Medical Education relating to educating the medical community in the United States.

1.10 **"Active Ingredient"** means any therapeutic agent, pharmaceutical product, biological pharmaceutical, biological therapeutic or other compound or ingredient and any Biosimilar for any of the foregoing, in each case whether used alone or in combination with any other compound, ingredient or material.

1.11 **"AdvaMed Code of Ethics"** means the American Medical Technology Association Code of Ethics, as hereafter amended from time to time.

1.12 **"Affiliate"** means, with respect to any Person, any other Person that directly, or indirectly through one or more intermediates, controls, is controlled by or is under common control with a specified Party at any time during the Term, only for so long as such control exists. For such purposes, "control," "controlled by" and "under common control with" shall mean the possession of the power to direct or cause the direction of the management and policies of such Person, directly or indirectly, whether through the ownership of voting equity, voting member or partnership interests, control of a majority of the board of directors or other similar body, by contract or otherwise. In the case of a corporate entity, the direct or indirect ownership of more than fifty percent (50%) of its outstanding voting securities or the ability otherwise to elect a majority of the board of directors or other managing authority of the entity shall in any event be presumptively deemed to confer control, it being understood that the direct or indirect ownership of a lesser percentage of such securities shall not necessarily preclude the existence of control.

1.13 **"Agent"** means any Third Party that is hired by, licensed by, sublicensed by or otherwise contractually associated with a Party during the Term of this Agreement to the extent useful or necessary for the Party to fulfill its obligations under this Agreement.

1.14 **"Agreement"** means this Collaboration and License Agreement, all amendments and supplements to this Collaboration and License Agreement and all schedules and exhibits to this Collaboration and License Agreement.

1.15 **"Alliance Manager"** has the meaning set forth in Section 3.3.

1.16 **"Alopecia Areata"** means any disease or condition listed in ICD-10, Chapter XII, Section L63.

1.17 **"AMA"** has the meaning set forth in Section 5.4(a).

1.18 **"Applicable Law"** means all applicable laws, statutes, rules, regulations, orders, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign, including all such laws, statutes, rules, regulations, orders, ordinances and other pronouncements having the effect of law pertaining to the medical device industry or the healthcare industry and all anti-bribery or anti-corruption laws, including the United States Food, Drug and Cosmetic Act of 1938, the United States Public Health Service Act, the United States Social Security Act, the United States Federal Anti-Kickback Statute, the Health Insurance Portability and Accountability Act of 1996, the United States Civil Monetary Penalties Law, the United States Federal False Claims Act, the administrative False Claims Law provisions related to false statements, representations, covering up or presenting a false claims for services which are paid for in whole or in part by a federal health care program, including a state health care program receiving some federal funds, the United States Foreign Corrupt Practices Act, all laws and regulations related to the collection, use, disclosure and protection of Personal Information, including HIPAA, and GDPR, and their implementing regulations and all state and foreign equivalents thereof.

1.19 **"Atopic Dermatitis"** means any disease or condition listed in ICD-10, Chapter XII, Sections L20-L30.

1.20 **"Authorized Representatives"** has the meaning set forth in Section 3.2(d).

1.21 **"Biologics License Application"** or **"BLA"** means (a) an application to introduce a biological product into interstate commerce, submitted by LEO Pharma to the FDA or applicable Regulatory Authority, and (b) any amendment or supplement thereto (including a supplemental BLA (**"sBLA"**)).

1.22 **"Biosimilar"** means, with respect to a particular therapeutic agent, pharmaceutical product, biological therapeutic or other compound or ingredient, in a particular country in the Territory, any pharmaceutical product that is claimed to be biosimilar to or interchangeable with such therapeutic agent, pharmaceutical product, biological therapeutic or other compound or ingredient (including a product that is the subject of an application submitted under Section 351(k) of the Public Health Service Act as set forth at 42 U.S.C. Chapter 6A, as may be amended from time to time) or for which a BLA otherwise references or relies on such

therapeutic agent, pharmaceutical product, biological therapeutic or other compound or ingredient or any corresponding foreign application in the Territory, including, with respect to the European Union, a marketing authorization application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval; and is approved for sale for at least one indication that is the same as an indication for which such agent, pharmaceutical product, biological therapeutic or other compound or ingredient is approved for sale in such country.

1.23 **"Business Day"** means a day other than Saturday, Sunday or any other day on which commercial banks located in the Commonwealth of Massachusetts or the Kingdom of Denmark are authorized or obligated by Applicable Law to close.

1.24 **"Calendar Quarter"** shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31, provided, however, that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.

1.25 **"Calendar Year"** shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31, provided however, that (a) the first Calendar Year of the Term, shall begin on the Effective Date and end on December 31, 2019; and (b) the last Calendar Year of the Term shall end on the effective date of expiration or termination of this Agreement.

1.26 **"Cartridge"** means an empty container capable of being filled with a liquid drug product and sealed for the purpose of injecting such drug into a patient using the Device and that uses or incorporates Portal Know-How, Portal Patent Rights or Portal Platform Technology. The Cartridge includes an associated plunger (stopper), distal seal (container closure/pull tab) and any lubricating substance (e.g., silicone oil) used. For the avoidance of doubt, the Cartridge shall not include LEO Pharma's Drug, the Product, or methods of making or using LEO Pharma's Drug (including methods of treatment or administration).

1.27 **"CE Mark"** means a label affixed to a medical device evidencing regulatory approval in the European Union and that such device meets the general safety and performance requirements of the relevant European Medical Device Regulation 2017/745.

1.28 **"Change of Control"** means the occurrence of any of the following events: (i) an acquisition of a Party by another entity by means of any transaction or series of related transactions (including, without limitation, any reorganization, merger or consolidation but excluding any merger effected exclusively for the purpose of changing the domicile of the Party), or (ii) a sale of all or substantially all of the assets of a Party, so long as in either case the Party's stockholders of record immediately prior to such transaction will, immediately after such transaction, hold less than fifty percent (50%) of the voting power of the surviving or acquiring entity.

1.29 **"Clinical Trial"** means any human clinical study or trial of the Product conducted in the Territory and in accordance with Applicable Law, including bioequivalence trials,

Phase 1 Clinical Trials, Phase 2 Clinical Trials, Phase 3 Clinical Trials, Phase 4 Clinical Trials, and/or variations of such trials (e.g., Phase 1b, Phase 2/3).

1.30 **"Cloud-Based Connectivity System"** means a system for storing Data collected via the Product Interface.

1.31 **"CMC Data"** means any and all Information contained in, as well as data supporting, the Chemistry, Manufacturing and Control sections (or sections corresponding thereto) of an NDA, sNDA BLA, sBLA or other equivalent regulatory filing, relating to the Device, Cartridge and/or Product.

1.32 **"Commercialization"** means all activities undertaken relating to the commercial exploitation of the Product in the Territory, including (a) marketing the Product for sale in the Territory, including advertising, education, planning, marketing, promotion and post-launch medical activities such as Phase 4 Clinical Trials anywhere in the Territory, (b) importing the Product into a country or other jurisdiction within the Territory and exporting the Product from a country or other jurisdiction within the Territory and (c) distributing or selling, or offering to distribute or sell, the Product in the Territory and any related market and product support; provided, however, that "Commercialization" shall exclude Development activities. "Commercialize" shall have a corresponding meaning.

1.33 **"Commercial Launch"** means the first bona fide arm's length commercial sale of the Product by LEO Pharma, an Affiliate of LEO Pharma, Subcontractor of LEO Pharma or a Sublicensee of LEO Pharma to a Third Party (including any final sale to a distributor or wholesaler under any non-conditional sale arrangement) in a country where all applicable Regulatory Approval of such Product have been obtained by or on behalf of LEO Pharma for which revenue has been recognized; provided, however, that in no event shall any sale or distribution of the Product for use in a Clinical Trial be deemed a Commercial Launch.

1.34 **"Commercially Reasonable Efforts"** means, with respect to any task or objective under this Agreement, the level of efforts and resources (including the promptness with which such efforts and resources would be applied) no less than the efforts and resources commonly used in the pharmaceutical industry and/or medical device industry for compounds or products of similar commercial potential at a similar stage in its development or product life as the Product. Commercially Reasonable Efforts shall be determined on a country-by-country (or region-by-region, where applicable) and indication-by-indication basis. With respect to any task or objective related to the Product (or any component thereof), it is understood that the level of efforts required to meet the above standard may change over time if there are changes in the status of the Product (or any component thereof) or in any of the following criteria applicable to the Product: market, commercial and profitability potential, efficacy, safety, regulatory status and labeling, the competitiveness of alternative products and procedures under development or in the marketplace, and the patent and other proprietary position of the Product, and other relevant factors. Notwithstanding the foregoing, the exercise of "Commercially Reasonable Efforts" will not require any party to pay money to obtain a consent to the transactions contemplated hereby from a third party to a Contract unless the payment is required pursuant to the terms of the applicable Contract with such third party in order to obtain such consent.

1.35 **"Confidential Information"** has the meaning set forth in Section 14.1.

1.36 **"Control"** by a Party means, with respect to any item of Information, Patent, Patent Application, Know-How or other Intellectual Property right, possession (including ownership) by such Party, including its Affiliates, of the ability (without taking into account any rights granted by one Party to the other Party under the terms of this Agreement) to grant access, a license or a sublicense to such Information, Patent, Patent Application, Know-How or other Intellectual Property right without violating the terms of any agreement or other arrangement with, or necessitating the consent of, any Third Party, at such time that the Party would be first required under this Agreement to grant the other Party such access, license or sublicense and at no cost to the Party granting the rights unless the Party being granted the rights agrees to pay any such costs (including milestones and royalties) associated with such grant.

1.37 **"Damages"** has the meaning set forth in Section 13.1.

1.38 **"Data"** means all data and information collected by or through the Product or Product Interface (including any Cloud-Based Connectivity System) or in connection with any Clinical Trial or provided by any customer in connection with use of the Product or Product Interface (including any Cloud-Based Connectivity System), including any Personal Information, including all such data and information (a) furnished, disclosed or otherwise made available to Portal, directly or indirectly, by or on behalf of LEO Pharma pursuant to this Agreement or (b) collected, processed or stored by or through any Product (including any Personal Information that is independently collected by Portal or that relates to a customer or other user of the Product.

1.39 **"Develop"** or **"Development"** means all activities relating to the research or development of the Product and/or obtaining worldwide Regulatory Approval of the Product and all manufacturing activities undertaken prior to Commercialization (including those activities reasonably required for the scale-up of Manufacturing processes or equipment in preparation for commercial supply of Product**)**. This includes, for example, (a) preclinical testing, toxicology, formulation, clinical studies, including Clinical Trials, and regulatory affairs, (b) all applicable Device design control activities, including human factors engineering, risk management and design transfer, and (c) manufacturing process development for bulk and finished forms of the Device or the Product, as applicable, production of clinical supply of Product, and manufacturing and quality assurance technical support activities prior to the commencement of Commercial Launch, but excludes Manufacturing for Commercialization purposes.

1.40 **"Development Plan"** means the written plan covering all planned Development of the Product, attached hereto as Exhibit 1.40 and incorporated herein by reference, as amended from time to time.

1.41 **"Device"** means a needle-free, computer-controlled delivery device capable of injecting viscous therapeutic agents that uses or incorporates Portal Know-How, Portal Patent Rights or Portal Platform Technology whether or not such device operates in conjunction with the Product Interface. For the avoidance of doubt, Device does not include LEO Pharma's Drug (including methods of treatment or administration).

1.42 **"Disputes"** has the meaning set forth in Section 19.11(a).

1.43 **"DMF"** means Drug Master File maintained with the FDA and the equivalent thereof, if any, in jurisdictions outside the United States.

1.44 **"Dollar"** means a United States Dollar, and "$" shall be interpreted accordingly.

1.45 **"EMA"** means the European Medicines Agency, or any successor thereto, which coordinates the scientific review of human pharmaceutical products under the centralized licensing procedure in the European Union.

1.46 **"European Union"** or **"EU"** means the countries that are members of the European Union as of the Effective Date of this Agreement or that become members of the European Union thereafter. For clarity, for purposes of this Agreement, the United Kingdom shall be considered to be a member of the EU regardless.

1.47 **"Exploitation"** or **"Exploit"** means, with respect to the Product, the making, having made, using, having used, selling, having sold, offering for sale and/or otherwise disposing of, holding or keeping (whether for disposal or otherwise) of the Product, including, all discovery, research, Development (including the conduct of Clinical Trials), Commercialization, registration, modification, enhancement, improvement, Manufacturing, labeling, storage, formulation, exportation, importation, optimization, transportation and other activities related thereto conducted pursuant to this Agreement. **"Exploitation"** means the act of Exploiting.

1.48 **"FDA"** means the United States Food and Drug Administration, or any successor thereto, having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products, delivery systems and medical devices in the United States.

1.49 **"Field"** has the meaning set forth in Section 2.1.

1.50 **"First Commercial Sale"** means, with respect to the Product in any country in the Territory, the first (1st) sale or license by LEO Pharma, its Affiliates, Subcontractors or Sublicensees to a Third Party (other than a Subcontractor or Sublicensee) in a bona fide arm's-length transaction for distribution, use, or consumption of any such Product for which Net Sales has been recognized in any country in the Territory.

1.51 **"Force Majeure Event"** has the meaning set forth in Section 19.4.

1.52 **"GAAP"** means United States generally accepted accounting principles consistently applied.

1.53 **"GDPR"** means the General Data Protection Regulation 2016/679 of the European Union.

1.54 **"Good Clinical Practices"** or **"GCP"** means the standards, practices and procedures set forth in the guidelines entitled in "Good Clinical Practice: Consolidated Guideline," including related regulatory requirements imposed by the FDA and (as applicable) any equivalent or similar standards in jurisdictions outside the Territory.

1.55 **"Good Laboratory Practices"** or **"GLP"** means the regulations set forth in 21 C.F.R. Part 58 and the requirements expressed or implied thereunder imposed by the FDA and (as applicable) any equivalent or similar standards in jurisdictions outside the Territory.

1.56 "**Good Manufacturing Practices**" or **"GMP"** means the regulations set forth in 21 C.F.R. Parts 210–211 and 820, Quality System Regulations and the requirements thereunder imposed by the FDA, and, as applicable, any similar or equivalent regulations and requirements in jurisdictions outside the Territory.

1.57 **"Governmental Authority"** or **"Governmental Authorities"** means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, instrumentality, agency, bureau, branch, office, commission, council, court or other tribunal**)**.

1.58 **"HIPAA"** means the United States Health Insurance Portability and Accountability Act of 1996, the health information privacy and security provisions of the United States Health Information Technology for Economic and Clinical Health Act, and the regulations and other guidance issued thereunder, including but not limited to the Privacy, Security, Breach Notification, and Enforcement Rules at 45 C.F.R. Parts 160 through 164.

1.59 **"IAS"** means International Accounting Standards.

1.60 **"ICD-10"** means the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10)-WHO (version 2016**)**.

1.61 **"IFRS"** means International Financial Reporting Standards as promulgated by the International Accounting Standards Board (**"IASB"**).

1.62 **"IL-13 Therapeutic Agent"** means any pharmaceutical product, whether currently marketed or in development, that targets or binds to IL-13 or any IL-13 receptor, or otherwise inhibits IL-13 signaling.

1.63 **"Improvements"** means any improvements, modifications, discoveries, inventions, developments, enhancements, and/or derivative works, including any and all Intellectual Property rights associated therewith, whether or not patentable or registrable or otherwise protectable.

1.64 **"IND"** means (a) an Investigational New Drug application as defined in the United States Federal Food, Drug, and Cosmetic Act, as amended, and applicable regulations promulgated hereunder by the FDA, (b) a clinical trial authorization application for a product filed with a Regulatory Authority in any other regulatory jurisdiction outside the United States, the filing of which (in the case of (a) or (b)) is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction, or (c) documentation issued by a Regulatory Authority that permits the conduct of clinical testing of a product in humans in such jurisdiction.

1.65 **"Indemnified Party"** has the meaning set forth in Section 13.3(a).

1.66 **"Indemnifying Party"** has the meaning set forth in Section 13.3(a).

1.67 **"Information"** means information, ideas, inventions, discoveries, concepts, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, designs, drawings, computer programs, skill, experience, documents, apparatus, results, clinical and regulatory strategies, test data, including pharmacological, toxicological and clinical and non-clinical data, analytical and quality control data, manufacturing data and descriptions, Patent and legal data, market data, financial data or descriptions, devices, assays, chemical formulations, specifications, compositions of matter, product samples and other samples, physical, chemical and biological materials and compounds, and the like, in written, electronic or other form, now known or hereafter developed, whether or not patentable, to the extent that the foregoing is not publicly known.

1.68 **"Intellectual Property"** means any of the following, whether existing now or in the future anywhere in the world: (a) Patents and Patent Applications; (b) Trademarks, copyrights, design rights (including unregistered designs), database rights and registrations and applications for any of the foregoing and all moral rights associated with any of the foregoing; and (c) Information.

1.69 **"Inventions"** has the meaning set forth in Section 10.2(a).

1.70 **"JDC"** has the meaning set forth in Section 3.1.

1.71 **"Joint Intellectual Property"** has the meaning set forth in Section 10.2(a).

1.72 **"Joint Inventions"** has the meaning set forth in Section 10.2(a).

1.73 **"Joint Patent Rights"** has the meaning set forth in Section 10.3(a).

1.74 **"LEO Pharma"** has the meaning set forth in the Preamble.

1.75 **"LEO Pharma's Drug"** has the meaning set forth in Section 2.1.

1.76 **"Know-How"** means, with respect to a Party, Information and Inventions Controlled by such Party. Know-How excludes any Information contained within a Party's Patents.

1.77 **"MAA"** means a marketing authorization application filed with the EMA for Regulatory Approval to import, market and sell the Product in the European Union.

1.78 **"MAF"** means a device master file submitted to the FDA Center for Devices and Radiological Health (CDRH) (or any equivalent thereof, in any jurisdictions outside the United States) that is used in support of premarket submissions to provide confidential detailed information about establishments, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more medical devices.

1.79 **"Manufacture"** or **"Manufacturing"** means the activities to be performed by Portal and LEO Pharma in connection with the manufacture, testing (including quality control,

quality assurance and lot release testing), bulk packaging and/or storage of LEO Pharma's Drug, the Device, and/or the Product, as applicable.

1.80 **"Manufacturing and Supply Agreement"** has the meaning set forth in Section 8.2.

1.81 **"Manufacturing Process"** has the meaning set forth in Section 12.2.

1.82 **"Milestone Payments"** has the meaning set forth in Section 7.3.

1.83 **"M.I.T."** means the Massachusetts Institute of Technology.

1.84 **"M.I.T. Agreement"** means the Exclusive Patent License Agreement dated January 30, 2014 between M.I.T. and Portal, as amended through Initial, First, Second, Third and Fourth Amendments thereto, effective respectively on February 14, 2014, July 2, 2014, August 27, 2014, July 8, 2015, and February 7, 2017.

1.85 **"NDA"** means (a) an application to introduce a drug product into interstate commerce, submitted by LEO Pharma to the FDA or applicable Regulatory Authority, and (b) any amendment or supplement thereto (including a supplemental NDA (**"sNDA"**)).

1.86 **"Negotiation Period"** has the meaning set forth in Section 2.2(a)(iii**)**.

1.87 **"Net Sales"** means the gross amount invoiced by LEO Pharma, its Affiliates, Subcontractors or Sublicensees to Third Parties throughout the Territory for sales of the Product in bona fide arm's-length transactions, less (a) sales returns and allowances, including trade, quantity and cash discounts and any other adjustments, including those granted on account of price adjustments, billing errors, rejected goods, damaged goods, returns (including as a result of recalls), rebates, chargeback rebates, fees, reimbursements or similar payments granted or given to wholesalers or other distributors, buying groups, healthcare insurance carriers or other institutions and any amounts allowed or credit related thereto, (b) accrued allowances for normal and customary trade, quantity and cash discounts, (c) freight, postage, shipping and applicable insurance charges, to the extent same are separately itemized in the invoice price and charged to the buyer, (d) the lower of one percent (1%) or the actual loss experience of LEO Pharma in respect of bad debts written off, provided, however, that such amount shall not exceed $1,000,000 on an annual basis, (e) customs or excise, duties, sales, withholding and similar taxes (including, value added or import/export taxes and sales taxes, but excluding taxes based on income), if any, imposed on the Product or sale thereof, (f) any payment in respect to sales to any Governmental Authorities in respect of any government subsidized program, including Medicare and Medicaid rebates and programs mandated by any agency thereof, and (g) any item substantially similar in character and/or substance to the above, all as determined in accordance with IFRS or IAS on a basis consistent with LEO Pharma's annual audited financial statements. In addition, Net Sales by LEO Pharma hereunder are subject to the following:

(1) Any transfer, sale or other disposal of the Product by LEO Pharma to an Affiliate, Subcontractor or Sublicensee of LEO Pharma shall not be included in Net Sales; in such case, Net Sales shall be calculated as above on the value charged or invoiced on the first bona fide arm's length sale to a Third Party;

(2) If LEO Pharma or its Affiliates, Subcontractors or Sublicensees make a sale or other disposition of the Product to a customer in a particular country (i) other than on normal commercial terms, then the Net Sales of the Product shall be deemed to be "the fair market value" of such Product on a country-by-country basis or (ii) as part of a package of products and services, then the Net Sales of the Product shall be determined on a country-by-country basis by mutual agreement of the Parties in good faith taking into account the relative value contributions of the Product and the other products in the Product Portfolio, as reflected in their individual sales prices (and in case of disagreement, such dispute shall be referred for resolution in accordance with Section 3.2(d)); and

(3) Use of the Product in a Clinical Trial or a pre-clinical study or other Development activities or disposal of the Product for non-profit purposes of a commercially reasonable program shall not give rise to any deemed sale for purposes of this definition.

1.88 **"OIG"** means the Office of the Inspector General.

1.89 **"Other Drug"** means any IL-13 Therapeutic Agent and any Biosimilar therefore or any Active Ingredient, in each case in the Field, or any other therapeutic agent, pharmaceutical product, biological therapeutic or other compound or ingredient, including any Biosimilar, that competes with any of the foregoing to treat patients in the Field, other than LEO Pharma's Drug.

1.90 **"Party"** or **"Parties"** has the meaning set forth in the Preamble.

1.91 **"Patent"** means (a) letters patent (or other equivalent legal instrument), including utility and design patents and industrial design registrations, and including any extension, substitution, registration, confirmation, reissue, re-examination or renewal thereof and (b) all foreign or international equivalents of any of the foregoing in any country in the Territory.

1.92 **"Patent Application"** means (a) an application for letters patent or design registration, including a reissue application, a re-examination application, a provisional application, a continuation application, a continued prosecution application, a continuation-in-part application, a divisional application or any equivalent thereof that is pending at any time during the Term of this Agreement before a government Patent agency and (b) all foreign or international equivalents of any of the foregoing in any country in the Territory.

1.93 **"Person"** means any individual, sole proprietorship, partnership, joint venture, trust, unincorporated association, corporation, limited liability company, entity or governmental authority (whether foreign, federal, state, county, city or otherwise, including any instrumentality, division, agency or department thereof and any Regulatory Authority**)**.

1.94 **"Personal Information"** means all sensitive personal information or personally identifiable information (as those terms are defined under Applicable Law), including names, addresses, electronic mail addresses, customer account information, health information, biometric identifiers, IP addresses, phone numbers and any financial account numbers, including credit card, bank account or social security numbers.

1.95 **"Pharmacovigilance Agreement"** has the meaning set forth in Section 5.1.

1.96 **"Phase 1 Clinical Trial"** means any clinical study conducted on sufficient numbers of human subjects to establish that the Product is reasonably safe for continued testing and to support its continued testing in Phase 2 Clinical Trials. "Phase 1 Clinical Trial" shall include any clinical trial that would satisfy requirements of 21 C.F.R. § 312.21(a).

1.97 **"Phase 2 Clinical Trial"** means any clinical study conducted on sufficient numbers of human subjects that have the targeted disease or condition of interest to investigate the safety and efficacy of the Product for its intended use and to define warnings, precautions, and adverse reactions that may be associated with such pharmaceutical product in the dosage range to be prescribed. "Phase 2 Clinical Trial" shall include any clinical trial that would satisfy requirements of 21 C.F.R. § 312.21(b), including a Phase 2a Clinical Trial and Phase 2b Clinical Trial.

1.98 **"Phase 2a Clinical Trial"** means a Phase 2 Clinical Trial conducted mainly to identify the appropriate dose of an Active Ingredient for a particular indication or indications.

1.99 **"Phase 2b Clinical Trial"** means a Phase 2 Clinical Trial to determine initial efficacy, pharmacological effect, or dose range and/or regimen finding of an Active Ingredient before embarking on Phase 3 Clinical Trial.

1.100 **"Phase 3 Clinical Trial"** means any clinical study intended as a pivotal study for purposes of seeking Regulatory Approval that is conducted on sufficient numbers of human subjects to establish that the Product is safe and efficacious for its intended use, to define warnings, precautions, and adverse reactions that are associated with the Product in the dosage range to be prescribed, and to support Regulatory Approval of the Product or label expansion of such pharmaceutical product. "Phase 3 Clinical Trial" shall include any clinical trial that would or does satisfy requirements of 21 C.F.R. § 312.21(c), whether or not it is designated a Phase 3 Clinical Trial.

1.101 **"Phase 4 Clinical Trial"** means clinical study of the Product on human subjects commenced after receipt of Regulatory Approval of the Product for the purpose of satisfying a condition imposed by a Regulatory Authority to obtain Regulatory Approval, or to support the marketing of such pharmaceutical product, and not for the purpose of obtaining initial Regulatory Approval of the Product.

1.102 **"PhRMA Code"** means the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, as hereafter amended from time to time.

1.103 **"Portal"** has the meaning set forth in the Preamble.

1.104 **"Portal Know-How"** means all Know-How that is (a) Controlled by Portal as of the Effective Date or at any time during the Term of this Agreement that is not publicly known, even though parts thereof may be known, and (b) useful or necessary to develop, make, use, sell, offer for sale, import or export Product (or any portion thereof) for use in the Field (including to modify, create derivative works of, compile, host, operate, support and maintain the Product Interface and to collect, store, process and transmit Data through the Product Interface).

Portal Know-How includes Portal's interest in unpublished Inventions and unpublished Joint Inventions. Portal Know-How does not include Portal Patent Rights.

1.105 **"Portal Patent Rights"** means (a) the Patents listed in Exhibit 1.105, (b) any Patents that issue from the Patent Applications listed in Exhibit 1.105, (c) any Patents and/or Patent Applications that claim priority to a Patent or Patent Application listed in Exhibit 1.105, including any continuation, continued prosecution application, divisional, reissue or re-examination, Controlled by Portal as of the Effective Date or at any time during the Term, (d) any other Patent and/or Patent Application Controlled by Portal as of the Effective Date or at any time during the Term of this Agreement that claims a product, method, apparatus, material, manufacturing process or other technology necessary to develop, make, use, sell, offer for sale, import or export LEO Pharma's Drug, the Device, any Cartridge, the Product Interface, or the Product, and (e) any foreign equivalents of (a), (b), (c) or (d). Portal Patent Rights include, the Patents and Patent Applications licensed to Portal under the M.I.T. Agreement. Portal Patent Rights includes Portal's interest in Joint Patent Rights. Portal Patent Rights do not include Portal Know-How or Portal Platform Technology.

1.106 **"Portal Platform Technology"** means all Portal Know-How, any other Intellectual Property Controlled by Portal that is useful or necessary to develop, make, use, sell, offer for sale, import or export Product (or any portion thereof) for use in the Field (including to modify, create derivative works of, compile, host, operate, support and maintain the Product Interface and to collect, store, process and transmit Data through the Product Interface), and any other technology, article of manufacture, component, system, discovery, or invention Controlled by Portal that relates to the Device, any Device component (including Cartridge, controller, circuitry, software code, algorithms, electrical connections and fluid connections), the Product Interface and methods of making or using the Device or any Device components or the Product Interface (including methods of treatment or administration**)**. For the avoidance of doubt, Portal Platform Technology does not include LEO Pharma's Drug, or methods of making or using LEO Pharma's Drug (including methods of treatment or administration) or any Intellectual Property or Improvements relating thereto.

1.107 **"Portal Trademarks"** means the Trademarks set forth in Exhibit 1.107 and any other Trademarks of Portal that are Controlled during the Term of this Agreement by Portal for use with the Cartridge, the Device, the Product Interface and/or the Product.

1.108 **"Portal's Knowledge," "Knowledge of Portal"** or similar phrases mean the actual knowledge of each of Patrick Anquetil, Chris Barber and Bobby Dyer, and the knowledge that such individuals would have after reasonable due inquiry by such individuals.

1.109 **"Product"** means the combination of (a) LEO Pharma's Drug and (b) the Device and/or Cartridge, which Product is developed in accordance with and pursuant to this Agreement and which may consist of the 2x1mL System and/or the 1x2mL System, as the case may be. Product shall not include any products, including devices, that are not based upon or do not use or incorporate any of the Portal Platform Technology, other than LEO Pharma's Drug.

1.110 **"Product Interface"** means any online and/or mobile software application provided by or through Portal for use in connection with the Device, in source code and object code form.

1.111 **"Project"** means the collaborative Development of the Product to be conducted by or on behalf of Portal and LEO Pharma under this Agreement and according to the Development Plan and incorporated herein by reference.

1.112 **"Proof of Concept"** means, with respect to an Active Ingredient for any and all indications of Prurigo Nodularis, Alopecia Areata, and/or Vitiligo, (a) the first dosing of the first patient in a Phase 2b Clinical Trial or (b) if a Phase 2b Clinical Trial is not conducted, the receipt of topline results of a Phase 2 Clinical Trial.

1.113 **"Prurigo Nodularis"** means any disease or condition listed in ICD-10, Chapter XII, Section L28.1.

1.114 **"Psoriasis"** means any disease or condition listed in ICD-10, Chapter XII, Section L40.

1.115 **"Regulatory Approval"** means (a) approval by the FDA of a NDA, BLA or other applicable filing and satisfaction of related applicable FDA registration and listing requirements, if any, and (b) in any country other than the United States, approval by Regulatory Authorities having jurisdiction in such country of a single application or set of applications comparable to a NDA, BLA or other applicable filing and satisfaction of related applicable regulatory and listing requirements, if any, together with any other approval necessary to Manufacture and Commercialize the Product in such country, including any pricing approvals.

1.116 **"Regulatory Authority"** means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities, including, the FDA and the EMA, regulating or otherwise exercising authority with respect to the Exploitation of the Product in the Territory.

1.117 **"Remedy Plan"** has the meaning set forth in Section 12.2.

1.118 **"Representing Party"** has the meaning set forth in Section 11.1.

1.119 **"Restricted Period"** has the meaning set forth in Section 12.1.

1.120 **"ROFN Period"** has the meaning set forth in Section 2.2(a)(iii).

1.121 **"Subcontractors"** has the meaning set forth in Section 4.4.

1.122 **"Sublicensee"** means any person or entity, including Affiliates of LEO Pharma, to which LEO Pharma grants a sublicense as expressly set forth under this Agreement (other than Portal or its Affiliates).

1.123 **"System"** has the meaning set forth in Section 4.2.

1.124 **"Technology Transfer Process for Fill/Finish"** has the meaning set forth in Section 8.5.

1.125 **"Term"** has the meaning set forth in Section 17.1.

1.126 **"Territory"** means the entire world.

1.127 **"Third Party"** means any person or entity other than LEO Pharma, Portal, or an Affiliate of either of them.

1.128 **"Trademark"** means any word, name, symbol, color, designation or device or any combination thereof, whether registered or unregistered, including, any trademark, trade dress, service mark, service name, brand mark, trade name, brand name, logo or business symbol, all goodwill associated therewith and any registration or application for any of the foregoing, including any renewal or extension thereof.

1.129 **"Tralokinumab"** means the human monoclonal antibody targeting the cytokine IL-13, which was licensed to LEO Pharma for the treatment of skin diseases.

1.130 **"Valid Claim"** means (a) a claim of an issued and unexpired Patent included within the Portal Patents to the extent such claim has not expired or irretrievably lapsed or been abandoned, dedicated to the public, revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final order, from which no further appeal can be taken, and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise; or (b) a claim within a patent application has not been pending for more than seven (7) years from the earliest filing date to which such claim or the applicable patent application is entitled to claim priority and which claim has not been revoked, cancelled, withdrawn, held invalid or abandoned.

1.131 **"Vitiligo"** means any disease or condition listed in ICD-10, Chapter XII, Section L80.

2. LICENSE GRANTS

2.1 **Field.** The licensed "Field" shall mean the following:

(a) with respect to any IL-13 Therapeutic Agent (whether alone or in combination with any other compound, ingredient or material) and any Biosimilar therefore, any and all indications; and

(b) with respect to any Active Ingredient,

(i) any and all subtypes of Atopic Dermatitis;

(ii) any and all subtypes of Prurigo Nodularis, Alopecia Areata and/or Vitiligo; provided that, within three (3) years of LEO Pharma having completed Proof of Concept for an Active Ingredient for any of such subtypes under this Section 2.1(b)(ii), LEO Pharma shall notify Portal and confirm that LEO Pharma is taking

demonstrable steps towards developing a Product comprising such Active Ingredient for such subtypes, and if LEO Pharma fails to provide such notice for any specific Active Ingredient and subtype under this Section 2.1(b)(ii), use of such Active Ingredient for such subtype under this Section 2.1(b)(ii) shall be excluded from the Field (for the avoidance of doubt, such exclusion shall only apply to such Active Ingredient for use with respect to the specific subtypes specified by LEO Pharma in its notice to Portal for which the foregoing requirement is not met) and the license granted under Section 2.2(a)(i) for use of such Active Ingredient with respect to such subtype under this Section 2.1(b)(ii) shall expire;

(iii) any and all subtypes of Psoriasis; provided that LEO Pharma exercises the right of first negotiation pursuant to Section 2.2(a)(iv) and obtains an exclusive license to jointly develop and commercialize, under the Portal Platform Technology, the Portal Know-How and Portal Patent Rights, the Product for Psoriasis in the Territory; and

(iv) any other indications (up to a maximum of three (3) additional indications), to be added by the Parties at LEO Pharma's request under the exclusive license grant under Section 2.2(a)(i) and other terms that are substantially similar to the terms of this Agreement by mutual agreement of the Parties after negotiating in good faith; provided, however, that Portal has not entered into an exclusive partnership with any Third Party to develop the Portal Platform Technology for such other indication prior to the date LEO Pharma provides notice of its intent to exercise its rights under this clause (iv) with respect to such indication and which exclusive partnership remains in effect.

Such IL-13 Therapeutic Agents and Biosimilars therefore for any and all indications, and such Active Ingredients for any and all subtypes of Atopic Dermatitis, Prurigo Nodularis, Alopecia Areata, Vitiligo, Psoriasis and such other indications agreed between Portal and LEO Pharma pursuant to clause (iv), above, in each case, to the extent developed or commercialized by LEO Pharma (as of the Effective Date or at any time thereafter) and included in the Field, shall be collectively referred to as **"LEO Pharma's Drug"**. For clarity, LEO Pharma's Drug shall include Tralokinumab and any Biosimilars therefore, alone or in combination with any other compound, ingredient or material.

2.2 **License and Right of First Negotiation Granted to LEO Pharma.**

(a) Subject to the terms and conditions of this Agreement, Portal hereby grants to LEO Pharma:

(i) an exclusive (even as to Portal and its Affiliates), royalty-bearing license, with the right to grant sublicenses in accordance with Section 2.4, under the Portal Platform Technology, Portal Know-How and Portal Patent Rights, to fill the Cartridge with LEO Pharma's Drug or any Other Drug in the Field, and use, have used, promote, develop, offer to sell, sell, have sold, import, have imported, export, have exported, and market the Product (or the combination of the Device and/or Cartridges with any Other Drug) in the Field throughout the Territory solely in connection with Exploitation of the Product (or the combination of the Device and/or Cartridges with any Other Drug) in the Field throughout the Territory;

(ii) an exclusive (except with respect to Portal marketing the Product as agreed by the Parties), royalty-free license, under the Portal Trademarks, with the right to grant sublicenses in accordance with Section 2.4, throughout the Territory, to use and display the Portal Trademarks solely in connection with the Commercialization of the Product in the Field throughout the Territory, as provided under and in accordance with Article 16;

(iii) (A) a non-exclusive, royalty-bearing license, with the right to grant sublicenses in accordance with Section 2.4, under the Portal Platform Technology, Portal Know-How and Portal Patent Rights, to fill the Cartridge with LEO Pharma's Drug for any other indications that are outside the Field, and use, have used, promote, develop, offer to sell, sell, have sold, import, have imported, export, have exported, and market the Product for such other indications outside the Field throughout the Territory solely in connection with Exploitation of the Product outside the Field throughout the Territory (for the avoidance of doubt, this non-exclusive license only applies to LEO Pharma's Drug for which LEO Pharma has exclusive license rights in the Field under Section 2.2(a)(i)); provided, however, that Portal has not entered into an exclusive partnership with any Third Party to develop the Portal Platform Technology for such other indication prior to the date LEO Pharma provides notice of its intent to exercise this license with respect to an indication and which exclusive partnership remains in effect, and (B) a non-exclusive, royalty-free license, under the Portal Trademarks, with the right to grant sublicenses in accordance with Section 2.4, throughout the Territory, to use and display the Portal Trademarks solely in connection with the Commercialization of such Product outside the Field throughout the Territory, as provided under and in accordance with Article 16; and

(iv) for two (2) years following the Effective Date (such two (2) year period, the **"Negotiation Period"**), a right of first negotiation to obtain for extra consideration an exclusive (even as to Portal and its Affiliates), royalty-bearing license, with the right to grant sublicenses in accordance with Section 2.4, under the Portal Platform Technology, the Portal Know-How and Portal Patent Rights, to fill the Cartridge with LEO Pharma's Drug, and use, have used, promote, develop, offer to sell, sell, have sold, import, have imported, export, have exported, and market the Product for Psoriasis throughout the Territory solely in connection with Exploitation of the Product for Psoriasis throughout the Territory. During the Negotiation Period, Portal shall provide to LEO Pharma all information in Portal's Control as reasonably necessary or useful for LEO Pharma to evaluate its interest in the Exploitation of the Product for Psoriasis throughout the Territory. Upon receipt by Portal of written notice of intent to negotiate from LEO Pharma, Portal shall negotiate solely and in good faith with LEO Pharma until the earliest of (a) the date that the Parties enter into a written agreement with respect to the license contemplated by this Section 2.2(a)(iv), (b) the date that LEO Pharma, in its sole discretion, provides written notice to Portal that it is no longer interested in the Exploitation of the Product for Psoriasis throughout the Territory, or (c) the expiration of the Negotiation Period (the **"ROFN Period"**). If the Parties are unable to agree on substantive terms for the license described in the first sentence of this Section 2.2(a)(iv) during the ROFN Period, then LEO Pharma shall promptly reduce to writing its last offer to Portal and provide such writing to Portal, and Portal shall be free to enter into an agreement with a Third Party for the license contemplated by this Section 2.2(a)(iv); provided that the terms of any such agreement with

a Third Party entered into by Portal during the period commencing on the expiration of the ROFN Period and ending on the six (6) month anniversary of such expiration, when taken as a whole, shall be no more favorable to the Third Party than those included in the written offer from LEO Pharma delivered to Portal pursuant to this Section 2.2(a)(iv).

2.3 **Certain Covenants.** Each Party covenants and agrees that (a) it shall not, and it shall cause its Affiliates and Sublicensees and Subcontractors not to, use or practice the Intellectual Property rights licensed to it under this Agreement except as expressly permitted by this Agreement and (b) any use or practice of the Intellectual Property rights licensed to it under this Agreement (except as expressly permitted by this Agreement) that results in material harm to the other Party shall constitute a material breach of a material obligation of this Agreement.

2.4 **Sublicense Rights.** LEO Pharma's right to grant sublicenses under the licenses granted to it under Section 2.2, shall be subject to the following: (a) each Sublicensee shall agree to be bound by all of the applicable terms and conditions of this Agreement; (b) the terms of each sublicense granted by LEO Pharma shall provide that the Sublicensee shall be subject to the terms and conditions of this Agreement; (c) LEO Pharma's grant of any sublicense shall not relieve LEO Pharma from any of its obligations under this Agreement; (d) LEO Pharma shall remain jointly and severally liable for any breach of a sublicense by a Sublicensee to the extent that such breach would constitute a breach of this Agreement, and any breach of the sublicense by the Sublicensee shall be deemed a breach of this Agreement LEO Pharma to the extent that such breach would constitute a breach of this Agreement; and (e) LEO Pharma will notify Portal of the identity of any Sublicensee, and the territory in which it has granted such sublicense, promptly after entering into any sublicense.

2.5 **No Implied Rights or Licenses.** Neither Party grants to the other Party any rights or licenses in or to any Patent or other Intellectual Property right, whether by implication, estoppel or otherwise, except to the extent expressly provided for under this Agreement.

2.6 **Covenant Not to Sue.** During the term of this Agreement, LEO Pharma agrees that it will not, and LEO Pharma shall cause its Affiliates and Sublicensees and Subcontractors not to, assert against Portal, its subsidiaries, Affiliates or Subcontractors, any claim, or institute any action or proceeding, whether at law or equity, under any Intellectual Property rights, including Patents or Patent Applications, owned by LEO Pharma or any of its Affiliates based on Portal's, its Affiliates' or Subcontractors' development, manufacture, use, practice, importation or sale of the Device or the Product in the Field and in the Territory pursuant to this Agreement. This covenant shall be binding upon, and inure to the benefit of, the Parties, their successors, and assigns.

2.7 **Reserved Rights.** This Agreement is subject to the rights reserved by the Massachusetts Institute of Technology under the M.I.T. Agreement or by the United States government under Title 35 of the United States Code Sections 200 through 204.

3. GOVERNANCE

3.1 **General.** Promptly after the Effective Date, the Parties shall establish a joint development committee (the **"JDC"**) in accordance with Section 3.2(a), which shall have the

responsibilities set forth in this Article 3. The representatives of each Party on the JDC shall be responsible for ensuring that their decisions and actions are consistent with the views of, and have been approved by, the Party that appointed them. Notwithstanding anything herein to the contrary, Portal shall not appoint to the JDC any Person employed by or associated with Sanofi-Aventis U.S. LLC or any of its Affiliates (including, Sanofi Sunrise) or any other direct or indirect competitor of LEO Pharma, even if such Person is a director or external advisor to Portal or is otherwise employed by or associated with Portal.

3.2 **Joint Development Committee.**

(a) Composition. Each Party shall appoint, within twenty (20) Business Days of the Effective Date, three (3) of its employees (or, with respect to LEO Pharma, its employees or the employees of its Affiliates) to serve on the JDC. LEO Pharma shall appoint the initial chairperson of the JDC, who shall serve in such capacity for a period of twelve (12) months commencing on the date of the first meeting of the JDC. Thereafter, the member of the JDC who shall serve as the JDC chairperson shall be designated alternately by each Party, with each chairperson serving for a period of twelve (12) months. Each Party may replace its JDC representatives by written notice to the other Party.

(b) Responsibilities. The JDC shall oversee and monitor the Development activities to be conducted hereunder, including reviewing and discussing material decisions and key activities that relate to the coordination, review and consultation of Development efforts pursuant to this Agreement. Without limiting the generality of the foregoing, the JDC shall: (i) ensure the coordination of the Development of the Product, and all associated regulatory activities; (ii) review the Development activities and obligations of the Parties under this Agreement, including under the Development Plan; (iii) review all material data arising in the course of the Development activities conducted pursuant to this Agreement by either Party; (iv) appoint subcommittees or working groups as it deems appropriate for carrying out the Development activities contemplated by this Agreement; (v) perform such other functions as appropriate to further the Development of the Product as determined by the Parties, including the periodic evaluation of performance against goals; and (vi) communicating with the Parties regarding all of the foregoing.

(c) Meetings and Voting. The JDC shall meet as soon as practicable following execution of this Agreement and thereafter as often as determined by the JDC members, but no less than once every Calendar Quarter, at times mutually agreed upon by the Parties. At least two (2) such meetings per Calendar Year must be held in person, and all other such meetings may be held by teleconference or videoconference. The location of the meetings of the JDC to be held in person shall alternate between sites designated by each Party, with the first such meeting to be designated by Portal and held in Boston, Massachusetts, U.S.A. Each Party shall bear all the expenses of its representatives on the JDC. The JDC chairperson shall issue an agenda reasonably in advance of each meeting and shall appoint one (1) member to keep accurate minutes of each meeting, which appointment shall be effective upon approval of the other Party, such approval not to be unreasonably withheld or delayed. The minutes of each meeting shall be circulated to the members of the JDC within fifteen (15) days after each meeting setting forth, among other things, a description, in reasonable detail, of the discussions at the meeting and a list of any actions, decisions, or determinations approved at such meeting. Each of LEO Pharma and Portal shall have

one (1) collective vote on the JDC regardless of how many representatives such Party has on the JDC, and any matter voted on shall require the unanimous vote of both Parties. If a disagreement among members of the JDC within the scope of the responsibilities of the JDC set forth in Section 3.2(b) remains unresolved for more than thirty (30) days after the JDC first addresses such matter (or such longer period as the Parties may mutually agree upon), such disagreement shall be resolved in accordance with Section 3.2(d). The JDC shall have no power to amend or waive compliance with this Agreement.

(d) Dispute Resolution. If the JDC is unable to resolve a disagreement among its members within the scope of its responsibilities set forth in Section 3.2(b) within thirty (30) days after it first addresses such matter (or such longer period as the Parties may mutually agree upon), then the Parties shall first attempt in good faith to resolve such disagreement by negotiation and consultation between themselves. If such disagreement is not resolved on an informal basis within thirty (30) days after one Party provides written notice to the other Party thereof (or such longer period as the Parties may mutually agree upon), then either Party may, by written notice to the other Party, refer such disagreement to an authorized person of each Party having authority to make decisions in such matters (the **"Authorized Representatives"**) of each Party for attempted resolution in accordance with Section 19.11(b); provided, however, that in the event the Authorized Representatives of each Party are unable to resolve such disagreement in accordance with Section 19.11(b), then (i) until all Development activities to be conducted by Portal pursuant to this Agreement have been completed, the dispute resolution procedures set forth in Sections 19.11(c) and 19.11(d) shall apply and (ii) otherwise, LEO Pharma shall have the final deciding vote.

3.3 **Alliance Managers.** Promptly after the Effective Date, each Party shall designate one (1) of its employees to act as its alliance manager (each, an **"Alliance Manager"**). Other than with respect to notices delivered pursuant to Section 19.5, the Alliance Managers shall be the primary day-to-day contact for the Parties regarding the activities contemplated by this Agreement and shall coordinate and facilitate the communication, interaction and cooperation of the Parties pursuant to this Agreement. Such Alliance Manager may be one of such Party's representatives on the JDC or any other employee such Party selects for this role. The Alliance Managers shall attend all meetings of the JDC and shall be responsible for assisting the JDC in performing its oversight responsibilities.

3.4 **Working Groups.** As provided in Section 3.2(b)(vi), the JDC may establish other subcommittees or working groups, as needed to further the purposes of this Agreement. The members of any subcommittee or working group shall have such expertise as appropriate to the activities of the respective subcommittee or working group, and the subcommittee or working group may invite personnel of the Parties having other relevant expertise to participate in discussions of the subcommittee or working group from time to time as appropriate to assist in the activities of the subcommittee or working group. In addition to the JDC meetings, a number of working groups with members from both LEO Pharma and Portal shall meet on a more frequent basis. No subcommittee or working group established pursuant to this Section 3.4 shall have the power to amend or waive compliance with this Agreement.

4. DEVELOPMENT PROGRAM

4.1 **Project.** LEO Pharma and Portal shall use Commercially Reasonable Efforts to collaborate in Developing the Product according to the Development Plan and the election made by LEO Pharma pursuant to Section 4.2. The Parties together shall work to develop the Device to be used in the Product and to craft the optimal patient experience related thereto, in each case in accordance with the design determined by LEO Pharma. In the event that either LEO Pharma or Portal proposes any reasonable modifications or changes to the Development Plan, then LEO Pharma and Portal shall negotiate such modifications and changes in good faith and mutually agree, in writing, upon the necessary modifications and changes to the Development Plan. Portal shall use Commercially Reasonable Efforts, and shall have primary control and direction in the Project for (a) Manufacturing Devices and Cartridges to meet LEO Pharma's reasonable Development-related needs; (b) testing and releasing Devices and Cartridges; (c) performing all design and development activities for the Device and/or the device constituent part of the Product required by Regulatory Authorities, including, without limitation, compliance with the design control requirements in the Quality System Regulation (21 C.F.R. § 820.30) and creation of a risk management file in accordance with ISO 14971; (d) performing all design verification testing of the Device and/or the device constituent part of the Product, including without limitation, performance testing, sterilization, shelf life, and biocompatibility; (e) preparing such documentation for use with an IND, BLA or NDA as LEO Pharma may reasonably request; (f) shipping Devices to Clinical Trial sites and servicing and maintaining any Devices used in Clinical Trials; and (g) submitting regulatory documentation with Regulatory Authorities in connection with the registration of the Device for use in the Product. LEO Pharma shall use Commercially Reasonable Efforts, and shall have primary control and direction in the Project, for (a) performing all drug compatibility and drug stability studies; (b) preparing and Manufacturing LEO Pharma's Drug; (c) preparing an (or more than one if required) IND for the Product and all related documentation; (d) filing and maintaining the IND(s); (e) preparing and submitting to Regulatory Authorities all regulatory documentation related to the Product; (f) CMC development of LEO Pharma's Drug; (g) planning, funding and executing all Clinical Trials and other clinical Development activities related to the Product, including human factor testing; (h) final packaging of the Product; and (i) preparing any BLAs or NDAs for the Product in the Territory and obtaining and maintaining all Regulatory Approvals for the Product in the Territory (including BLAs and NDAs) and, generally, for the Commercialization of the Product.

4.2 **Device Development.** After the Effective Date, LEO Pharma shall notify Portal in writing of its election, which shall be made in LEO Pharma's sole discretion, that the Product to be developed under the Development Plan shall consist of (a) a Device and Cartridge that is capable of delivering 2mL of LEO Pharma's Drug as a single injection (the **"1x2mL System"**), (b) a Device and Cartridge that is capable of delivering 2mL of LEO Pharma's Drug as two sequential injections (the **"2x1mL System**" and each of the 1x2 mL System and the 2x1 System a **"System"**), or (c) both the 1x2mL System and the 2x1mL System. Portal shall use Commercially Reasonable Efforts to Develop the System(s) selected by LEO Pharma. LEO Pharma may at any point after making its election pursuant to this Section 4.2, in its sole discretion, provide Portal with written notification to change its election, including to cease and/or commence to Develop a System under the Development Plan. Following the Effective Date, the Parties shall work together to discuss development and features of the Product Interface to be used with LEO Pharma's Drug. For clarity, Portal shall not be required to develop, provide or host a Cloud-Based

Connectivity System for use in connection with the Product Interface, and LEO Pharma shall not be required to use any Cloud-Based Connectivity System provided by or through Portal, unless the Parties agree in writing that Portal will do so after having agreed upon reasonable compensation to be paid by LEO Pharma to Portal and other terms in connection therewith.

4.3 **Standard of Performance.** Each Party, in performing its activities in connection with the Project, shall comply with all Applicable Laws, including where applicable, then-current GCP, GLP, and GMP.

4.4 **Subcontracting.** Except as otherwise expressly permitted by this Agreement, Portal shall not subcontract any of its obligations under this Agreement to any Third Party (including any Third Party contract research organization or Third Party contract manufacturing organization) without the express consent of LEO Pharma (provided via the JDC or, if provided otherwise, provided in writing), which consent shall not be unreasonably withheld or delayed. To the extent that either Party subcontracts any of its obligations under this Agreement to any Third Party, such Party shall remain responsible for the performance of such Third Party (each a **"Subcontractor"**) and shall (i) cause such Third Party to comply with the provisions of this Agreement in connection with such performance and (ii) first have obtained written confidentiality agreements with any such Subcontractors and written assignments of, or equivalent rights under, all Patent rights and know-how and other Intellectual Property that such Subcontractors may develop by reason of work performed under this Agreement.

5. REGULATORY MATTERS

5.1 **Pharmacovigilance Agreement.** The Parties shall, within sixty (60) days after being directed to do so by the JDC, convene a meeting to negotiate in good faith the terms and conditions of a pharmacovigilance agreement (the **"Pharmacovigilance Agreement"**), which shall establish all material economic, regulatory, business, technical and other terms under which the Parties shall collect, monitor, research, assess and evaluate information from healthcare providers and patients on the adverse effects, if any, of the Product, with a view to identifying new information about hazards associated with the Product and preventing harm to patients. The Parties shall exercise Commercially Reasonable Efforts to execute a mutually satisfactory Pharmacovigilance Agreement within ninety (90) days of the initial meeting convened to negotiate the terms and conditions of the Pharmacovigilance Agreement.

5.2 **Preparation of Regulatory Filings.** Each Party, at such Party's sole cost and expense unless otherwise provided for herein, shall be responsible for preparing, filing, and maintaining, and shall own, the regulatory filings relating to the Device, Cartridge, and Product as set forth below:

(a) At its expense, Portal shall use Commercially Reasonable Efforts to prepare and maintain regulatory submissions (MAFs or equivalent) covering the Device and Cartridge, and Portal shall own any such MAFs and shall control and have the final decision rights related to the contents of same. During the Term of this Agreement, Portal grants to LEO Pharma and its Sublicensees a right of reference to the MAFs for the Device and Cartridge owned by Portal to the extent necessary for, and for the purposes of, preparing, filing or maintaining INDs, BLAs, NDAs, MAAs and other regulatory filings relating to the Product in the Territory, including CMC

Data. Portal shall share with LEO Pharma documentation contained within the MAFs (redacted, if necessary in Portal's reasonable opinion), with the right to inspect, upon LEO Pharma's request. The Party that owns a regulatory filing shall be responsible for all interactions with Regulatory Authorities relating to such filing. The foregoing notwithstanding, all regulatory support reasonably required by LEO Pharma for regulatory filings will be provided to LEO Pharma by Portal for all countries where such filings are required, including in the United States even if a MAF is on file with the FDA.

(b) At its expense, LEO Pharma, its Affiliates and its Sublicensees shall use Commercially Reasonable Efforts to prepare, obtain and maintain all regulatory dossiers and Regulatory Approvals covering the Product in the Territory. Except as provided in Section 5.2(a), LEO Pharma or its designee shall be the owner of all such filings and shall be responsible for all interactions with Regulatory Authorities relating thereto; provided, however, that at all times during the Term hereof, Portal shall have the opportunity to participate in all meetings and other communications with Regulatory Authorities relating to the Device and/or Cartridge as it is used as a constituent part of the Product, at Portal's expense. In addition to LEO Pharma's other obligations under this Section 5.2(b), LEO Pharma shall keep Portal informed, on a regular basis (but no less frequently than once per Calendar Quarter) of regulatory filings related to the Product.

5.3 **Notice of Communication with Regulatory Authorities.** LEO Pharma shall be responsible for reporting all adverse events and handling all complaints and communications (including with Regulatory Authorities) relating to the Product, Portal shall be responsible for all complaints related to the Device and Cartridge, including in those countries where the CE Mark owner for the Device is required to communicate directly to Regulatory Authorities. Except as otherwise provided for in this Section 5.3, each Party shall provide quarterly summaries to the other Party of any oral or written communications to or from Regulatory Authorities on matters related to the Product or which may reasonably be deemed to impact Product Development, Manufacture, Commercialization or Regulatory Approval.

5.4 **Regulatory Compliance.**

(a) Each of Portal and LEO Pharma shall reasonably cooperate with the other Party in its efforts to ensure that all government price and gift reporting, sales, marketing and promotional practices with respect to the Product meet the standards required by Applicable Laws, as well as applicable guidelines concerning the advertising of prescription drug products, the OIG Compliance Guidance Program, the American Medical Association (the **"AMA"**) Guidelines on Gifts to Physicians, the PhRMA Code, AdvaMed Code of Ethics, and the ACCME Standards.

(b) LEO Pharma shall provide its employees and its contract sales force, if any, involved in sales, marketing, promotion, or price or gift reporting for the Product appropriate training on proper marketing and sales techniques, including restrictions on the promotion of "off label" use of medical devices. Such training may include, to the extent applicable and among other topics, FDA requirements and other state and federal regulations and guidelines concerning the advertising of prescription drug products, the OIG Compliance Guidance Program, the AMA Guidelines on Gifts to Physicians, the PhRMA Code, AdvaMed Code of Ethics, and the ACCME Standards. If requested by Portal, LEO Pharma shall provide a

written description (in general terms) of the training to Portal; provided however that such request shall not be made more frequently than on an annual basis.

(c) Each of Portal and LEO Pharma shall reasonably cooperate with the other Party to provide the other Party access to any and all information, data and reports required by the other Party in order to comply with Applicable Laws, including reporting requirements, in a timely and appropriate manner.

(d) Portal shall use reasonable efforts to endeavor to prepare and provide to LEO Pharma any data or other information covered by this Section 5.4 in accordance with methodologies specified by LEO Pharma, and shall advise LEO Pharma if there is any respect in which it has been unable to do so. If Portal has a question about whether a specific transaction or other event needs to be reported to LEO Pharma pursuant to this Section 5.4, Portal's obligation shall be satisfied by delivery of a true, complete and correct report of such transaction or other event, without a determination as to the proper reporting or legal characterization of such matter.

(e) LEO Pharma shall notify Portal in advance of submission of any material information provided by Portal pursuant to this Section 5.4 that LEO Pharma proposes to submit to any governmental entity. LEO Pharma further agrees to seek confidential treatment of any such information relating to Portal that it submits to any governmental entity to the extent permitted under any Applicable Laws.

(f) Portal and LEO Pharma shall confer with each other on a regular basis to discuss and compare their respective procedures and methodologies relating to each Party's compliance with any Applicable Laws or fulfillment of any other obligation contained in this Section 5.4. In the event that the Parties have different understandings or interpretations of this Section 5.4 or of the applicability of or standards required by any Applicable Law, then the Parties shall confer and seek to reach common agreement on such matters.

5.5 **Regulatory Documentation.** LEO Pharma shall own and retain all right, title and interest in and to all Regulatory Approvals and all regulatory documentation with respect to the Product, excluding the MAF for the Device and CE Mark therefor (and equivalents of the foregoing).

5.6 **Product/Device/Cartridge Recall.** The Manufacturing and Supply Agreement shall contain provisions acceptable to both Parties regarding (a) a Regulatory Authority's issuance or request of a recall or similar action in connection with the Product and (b) either Party's determination that an event, incident or circumstance has occurred which may result in the need for a recall, field correction or market withdrawal.

6. COMMERCIALIZATION

6.1 LEO Pharma shall be responsible for Commercialization in the Territory and, as between the Parties, shall book all sales of the Product in the Territory**.**

6.2 LEO Pharma shall use Commercially Reasonable Efforts to Commercialize the Product in the Territory; provided, however, that LEO Pharma shall not be required to Commercialize the Product in any such country to the extent it determines that such

Commercialization in such country is not commercially viable and, provided, further, however, that nothing in this Agreement shall restrict or be deemed to restrict LEO Pharma's right to commercialize LEO's Drug in any presentation (other than as a part of the Product) or in combination with any other product**.**

6.3 With the exception of Portal's Development and Manufacturing activities under this Agreement, LEO Pharma shall be responsible for its own costs and expenses incurred in connection with the Commercialization of Product in the Territory including: (a) developing and executing a Commercial Launch and pre-launch plan; (b) marketing and promotion; (c) booking sales and distribution and performance of related services; (d) handling all aspects of order processing, invoicing and collection, inventory and receivables; (e) publications; (f) providing customer support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures in all material respects to Applicable Law relating to the marketing, detailing and promotion of the Product in the Territory. LEO Pharma shall be solely responsible for the review and approval of, and shall have sole discretion with respect to, all promotional materials for compliance with Applicable Law, including submission, where appropriate, to the applicable Regulatory Authority.

6.4 Portal, at its own cost and expense, shall use commercially reasonable efforts to assist LEO Pharma in connection LEO Pharma's customer support activities pursuant to Section 6.3(f), including providing back office support as reasonably requested by LEO Pharma and assistance in connection with the investigation of any alleged defects or other issues with the Product**.**

7. PAYMENT OBLIGATIONS

7.1 **Upfront Payment.** In consideration for the licenses and other rights granted to LEO Pharma herein, upon the terms and conditions contained herein, LEO Pharma shall pay to Portal a one-time payment in an amount equal to twelve million Dollars ($12,000,000) within ten (10) days of the earlier of (a) the date on which LEO Pharma receives from the Danish tax authority approval of the filing of a Certificate of U.S. Tax Residency on United States Internal Revenue Service Form 6166 with respect to Portal, which LEO Pharma shall file with such Danish tax authority within three (3) Business Days of the Effective Date and (b) the date on which Portal waives in writing LEO Pharma's obligation to submit the certificate referenced in clause (a). Such payment shall be non-refundable and non-creditable.

7.2 **Development Funding.**

(a) Development Cost of 1x2mL System. If LEO Pharma elects to Develop a 1x2mL System pursuant to Section 4.2, then, upon the terms and conditions contained herein, LEO Pharma shall pay Portal a total amount of fifteen million Dollars **(**$15,000,000) (the **"1x2mL System Development Fee"**) in equal quarterly installments of one million five hundred thousand Dollars ($1,500,000), beginning on the date on which LEO Pharma delivers its written notice pursuant to Section 4.2 and continuing for ten (10) consecutive Calendar Quarters thereafter (with the first Calendar Quarter to run from the date of delivery of the written notice from LEO Pharma to Portal until the respective end date of such Calendar Quarter as defined in this Agreement) (the **"1x2mL System Development Period"**). Each such installment payment

shall be paid at the beginning of the respective Calendar Quarter and such payment shall be non-refundable and non-creditable. If, at any time during the 1x2mL System Development Period, LEO Pharma elects to cease the Development of the 1x2mL System, then LEO Pharma shall have no obligation to make any future installment payments towards the 1x2mL System Development Fee. Notwithstanding the aforementioned, in the event that LEO Pharma and Portal do not reach an agreement regarding the Exploitation of the Product for Psoriasis throughout the Territory pursuant to Section 2.2(a)(iv) for any reason and Portal grants a license to a Third Party, under the Portal Platform Technology, the Portal Know-How and Portal Patent Rights, for Psoriasis for which a Device and Cartridge that is capable of delivering 2mL of any therapeutic agent, pharmaceutical product, biological therapeutic or other compound or ingredient, that is useful to treat Psoriasis as a single injection shall be Developed, then the 1x2mL System Development Fee shall be reduced by fifty percent (50%) and Portal shall promptly refund to LEO Pharma any excess payment made by LEO Pharma therefore.

(b) Development Cost of 2x1mL System. If LEO Pharma elects to Develop a 2x1mL System pursuant to Section 4.2, then, upon the terms and conditions contained herein, LEO Pharma shall pay Portal a total amount of two million Dollars **(**$2,000,000) (the **"2x1mL System Development Fee"**) in equal quarterly installments of six hundred sixty-six thousand six-hundred and sixty-six Dollars and sixty-six cents ($666,666.66), beginning on the date on which LEO Pharma delivers its written notice pursuant to Section 4.2 and continuing for three (3) consecutive Calendar Quarters thereafter (with the first Calendar Quarter to run from the date of delivery of the written notice from LEO Pharma to Portal until the respective end date of such Calendar Quarter as defined in this Agreement) (the **"2x1mL System Development Period"**). Each such installment payment shall be paid at the beginning of the respective Calendar Quarter and such payment shall be non-refundable and non-creditable. If, at any time during the 2x1mL System Development Period, LEO Pharma elects to cease the Development of the 2x1mL System, then LEO Pharma shall have no obligation to make any future installment payments towards the 2x1mL System Development Fee. For clarity, in the event that LEO Pharma elects to have Portal Develop both a 1x2mL System and a 2x1mL System, LEO Pharma shall pay Portal both the 1x2mL System Development Fee and the 2x1mL System Development Fee.

7.3 **Milestone Payments.** LEO Pharma shall make the following non-refundable, non-creditable Milestone Payments (the **"Milestone Payments"**) to Portal within forty-five (45) days after achievement of the relevant milestone set out below. The milestones in this Section 7.3 are cumulative, such that under no circumstances is any single Milestone Payment to be deemed in lieu of, or to be substituted for, another Milestone Payment. For clarity, each Milestone Payment in this Section 7.3 relates to the relevant System chosen by LEO Pharma pursuant to Section 4.2 and is payable by LEO Pharma to Portal only once with respect to the achievement of any milestone under this Agreement irrespective of whether the milestone in question is later accomplished with respect to another System.

Milestone Event	Payment
Completion of a pharmacokinetic study in animals in which a Third Party determines that delivery of LEO Pharma's Drug via the Device	$1,000,000

is bioequivalent to delivery via a needle/syringe; the date of such completion being the date on which such Third Party provides the final Clinical Study Report to LEO Pharma, which shall include a statement that the bioequivalence criteria have been met and descriptions of attainment of pharmacokinetic endpoints and such safety experience as may have been observed.	
First dose for an enrolled human patient in a Clinical Trial	$2,000,000
Acceptance by the FDA of a BLA or NDA	$10,000,000
Submission to and Acceptance of the EMA for an eCTD compliant MAA	$5,000,000
Regulatory submission and Acceptance in Japan	$1,000,000
Regulatory Approval in the United States	$7,000,000
Regulatory Approval in EU	$4,000,000
Regulatory Approval in Japan	$2,000,000
Receipt of first Regulatory Approval in any jurisdiction in the Territory, other than the United States, EU and Japan	$1,000,000
Achievement of annual Net Sales of the Product for which LEO Pharma's Drug is Tralokinumab or any Biosimilar therefore, alone or in combination with any other compound, ingredient or material to be included in the calculation of Net Sales for the purpose of this Milestone Payment of at least $1,000,000,000	$50,000,000

7.4 **Royalties.**

(a) Subject to the other provisions of this Section 7.4 and the terms and conditions of this Agreement, in consideration for the grant of the license under the Portal Platform Technology, the Portal Patent Rights and Portal Know-How to LEO Pharma under Section 2.2(a), in consideration of Portal's active collaboration in and contributions to the Project, and as partial consideration for Portal's Manufacturing and supply of Devices and Cartridges, LEO Pharma shall pay Portal non-refundable and non-creditable royalties based on the aggregate annual Net Sales of all Products sold in all countries in the Territory in a Calendar Quarter to Third Parties by or on behalf of LEO Pharma, its Affiliates or Sublicensees, according to the following royalty rates (for the purposes hereof, "annual" means any complete calendar year period beginning on January 1 and ending on December 31):

Annual Net Sales in the Territory	Annual Royalty Rate
$0 - $500,000,000	[redacted]
$500,000,001 - $1,000,000,000	[redacted]
$1,000,000,001 – $2,000,000,000	[redacted]
> $2,000,000,000	[redacted]

Each royalty rate specified in the table above applies only to the corresponding incremental range of annual Net Sales in the table. A sample calculation of the royalty payments contemplated by this Section 7.4(a) is set forth on Exhibit 7.4. To the extent there is any inconsistency between the sample calculation set forth on Exhibit 7.4 and the text of this Section 7.4(a), this Section 7.4(a) shall control. In the event that there is no Valid Claim of Portal Patent Rights covering sold Product in a country at the time of Net Sales of such Product in such country, then the applicable royalty rate(s) payable on such Net Sales of such Product in such country shall be fifty percent (50%) of the rate(s) set forth in the table above; provided, however, that LEO Pharma shall have no obligation to pay royalties pursuant to this Section 7.4(a) as of and following the tenth (10^{th}) anniversary of the First Commercial Sale in such country.

(b) Portal shall be solely responsible for the payment of all amounts due and owing to M.I.T. under the M.I.T. Agreement with respect to the Territory.

7.5 **Payments.** Payments due under Section 7.4(a) shall be paid not later than forty-five (45) calendar days following the end of each Calendar Quarter with respect to Net Sales in such Calendar Quarter. Each payment under this Section 7.5 shall be accompanied by a written report showing, on a country-by-country basis, (a) the Calendar Quarter for which such payment applies, (b) the amount billed to Third Parties for Product during such Calendar Quarter, (c) the total deductions from the amount billed to arrive at Net Sales, (d) the quantities of all Product sold, and (e) the amount of royalties due. Any late payments under this Agreement shall bear interest at the prime rate of interest as reported on the first Business Day following the date payment is due in the "Money Rates" section of *The Wall Street Journal* (Eastern United States Edition).

7.6 **Currency of Payment.** All payments to be made under this Agreement shall be made in Dollars. Net Sales made in foreign currencies shall be converted into Dollars using the average of the month end daily currency exchange rates set forth in *The Wall Street Journal* (Eastern United States Edition) for each of the three calendar months included in the calendar quarter in which such Net Sales were made.

7.7 **Sublicensing.** In the event LEO Pharma grants a sublicense under Section 2.4 to a Sublicensee to make, use, import, offer to sell or sell Product, such sublicenses shall require the Sublicensee to account for and report its Net Sales of Product on the same basis as if such sales were Net Sales of Product by LEO Pharma, and LEO Pharma shall pay royalties on such sales as if the Net Sales of the Sublicensees were Net Sales of LEO Pharma.

7.8 **Costs and Expenses.** Except as otherwise expressly set forth in this Agreement, each Party shall bear its own costs and expenses incurred in connection with this Agreement, including all costs and expenses incurred in connection with the performance of its obligations under this Agreement.

7.9 **Accounting.**

(a) For the purposes of determining all costs and expenses hereunder, any cost or expense allocated by either Party to a particular category for the Product shall not also be allocated to another category for such Product, and any cost or expense allocated to the Product in a particular country shall not be allocated or allocable to another product of such Party in such country or the same Product in a different country.

(b) LEO Pharma agrees to determine Net Sales with respect to Product using its standard accounting procedures, consistent with GAAP or IFRS or IAS to the extent practical as if the Product was a solely owned product of LEO Pharma, except as specifically provided in this Agreement. In the case of amounts to be determined by Third Parties (for example, Net Sales by Sublicensees), such amounts shall be determined in accordance with GAAP or IFRS or IAS in effect in the country in which such Third Party is engaged. The Parties also recognize that such procedures may change from time to time and that any such changes may affect the definition of Net Sales. The Parties agree that, where such changes are economically material to either Party, adjustments shall be made to compensate the affected Party in order to preserve the same economics as are reflected under this Agreement under such Party's accounting procedures in effect prior to such change. Where the change is or would be material to one Party, the other Party shall provide an explanation of the proposed change and an accounting of the effect of the change on the relevant revenue, cost, or expense category.

(c) In the event of the payment or receipt of non-cash consideration in connection with the performance of activities under this Agreement, the Party engaging in such non-cash transaction shall advise the JDC of such transaction, including such Party's assessment of the fair market value of such non-cash consideration and the basis therefor. Such transaction shall be accounted for on a cash equivalent basis, as mutually agreed by the Parties in good faith.

7.10 **Withholding Tax.** Any Party required to make a payment to any Party under this Agreement shall be entitled to deduct and withhold from the amount otherwise payable such amounts to the extent it is required to deduct and withhold with respect to such payment under any provision of federal, state, local or foreign tax law. Such withheld amounts shall be treated for all purposes of this Agreement as having been paid to the Party on whose behalf it was withheld. No deduction shall be made to the extent the paying Party is timely furnished with necessary documents certifying that the payment is exempt from tax or subject to a reduced tax rate.

8. MANUFACTURE AND SUPPLY OF LEO PHARMA'S DRUG AND THE DEVICE, AND PROVISION OF RELATED SERVICES

8.1 **Clinical and Commercial Manufacturing of LEO Pharma's Drug.** LEO Pharma shall be solely responsible for all Manufacturing of clinical and commercial supplies of LEO Pharma's Drug, as well as all final packaging and labeling of Product (including where packaging of Product shall physically contain together LEO Pharma's Drug, Cartridges and Devices).

8.2 **Clinical and Commercial Manufacturing and Supply of Devices and Cartridges.** Within ninety (90) days after being directed to do so by the JDC, the Parties shall enter into an agreement governing the detailed terms and conditions of Portal's supply of Devices and Cartridges for use in the Development of Product and the terms and conditions of a commercial manufacturing and supply agreement (the **"Manufacturing and Supply Agreement"**), the key terms of which are set forth on Exhibit 8.2. Nothing in this Agreement or in the Manufacturing and Supply Agreement shall limit LEO Pharma's right to select a Third Party to fill and finish Cartridges (provided by Portal) at a LEO Pharma designated manufacturing facility.

8.3 **Manufacturing Expenditures.** LEO Pharma shall be responsible for all capital costs incurred in connection with the Manufacture of LEO Pharma's Drug and Product (excluding the Device and Cartridges), including building out manufacturing capacity for LEO Pharma's Drug and Product (excluding the Device and Cartridges) and final packaging of the Product. Portal shall be responsible for all capital costs incurred in connection with the Manufacture of the Device and Cartridges, including all costs associated with the set-up of the pilot and the scale-up of the manufacturing lines.

8.4 **Existing Supply Agreements**. For existing supply agreements, to the extent that the agreement provides Portal with the right, Portal shall require the third party supplier to permit the applicable health authorities to attend on the facilities for the purposes of performing GMP inspections in the event and to the degree that this is required by such authorities and shall require the third party supplier to provide, at the cost of Portal, reasonably necessary support in connection therewith.

8.5 **Technology Transfer for Fill/Finish of Cartridges.** At LEO Pharma's request, the Parties shall engage in a technology transfer process at LEO Pharma's sole expense (with LEO Pharma reimbursing Portal for Portal's actual out-of-pocket and FTE costs associated therewith) to enable LEO Pharma (or one of its Affiliates) or a Third Party selected by LEO Pharma to conduct the fill and finish the Cartridges, assemble the Cartridges with the Device to complete the Product and use and operate the Product Interface for commercial supply (the **"Technology Transfer Process for Fill/Finish"**). Portal shall perform all activities of the transferring facility and provide all assistance necessary for completing a successful Technology Transfer for Fill/Finish, and shall cause its Affiliates and Subcontractors to do the same. LEO Pharma shall perform, or shall cause its Affiliate or Third Party contract manufacturing organization to perform, at its sole cost, all activities of the receiving facility and take all reasonable actions necessary for completing a successful Technology Transfer for Fill/Finish.

9. RECORD KEEPING, RECORD RETENTION AND AUDITS

9.1 **Record Keeping.** Each Party shall, and shall require its Affiliates, Subcontractors and Sublicensees to, maintain records of all work conducted by such Party in connection with the activities and transaction contemplated by this Agreement in accordance with Applicable Law. Such records shall be complete and accurate and shall fully and properly reflect all such work done and all results achieved in sufficient detail and in good scientific manner appropriate for Patent and regulatory purposes. Each Party shall require its employees, consultants and contractors, and shall cause its Affiliates, Sublicensees and Subcontractors, as applicable, to disclose any Inventions relating to the Project in writing promptly after conception. LEO Pharma

shall keep complete and accurate records pertaining to the Development and Commercialization of Product in sufficient detail to permit Portal to verify the accuracy of calculations of all payments made under this Agreement.

9.2 **Record Retention.** The records to be maintained by the Parties under Section 9.1 shall be maintained for a minimum of five (5) years following the year in which the corresponding efforts or payments, as the case may be, were made under this Agreement or longer if required by Applicable Law.

9.3 **Audit Request.** Portal shall, at its expense (except as provided below), have the right to audit the records maintained by LEO Pharma under Section 9.1, solely for the purpose of confirming Net Sales and royalties for a period covering not more than the preceding three (3) Calendar Years. If Portal desires to audit such records, it shall engage an independent, certified public accountant reasonably acceptable to LEO Pharma, to examine such records under conditions of confidentiality. Such accountant shall be instructed to provide to Portal a written report verifying any report made or payment submitted by LEO Pharma during such period, but shall not disclose to the Portal any confidential Information of LEO Pharma not necessary therefor. Such audits shall be conducted during normal business hours, at such place or places where such records are customarily kept, upon reasonable prior written notice to LEO Pharma; provided, however, that (a) such audits do not unreasonably interfere with the business or operations of LEO Pharma, (b) LEO Pharma is not under any obligation to disclose to Portal any information the disclosure of which is prohibited by Applicable Law or that would result in the waiver of any attorney-client, work-product or other applicable privilege and (c) such audits shall not occur more frequently than once per Calendar Year. No accounting period of LEO Pharma shall be subject to audit more than one time by Portal. The expense of such audit shall be borne by Portal; provided, however, that, if an underpayment of royalties by LEO Pharma was greater than five percent (5%) is discovered, then reasonable out-of-pocket expenses shall be paid by LEO Pharma. If such accountant concludes that additional payment amounts were owed to Portal during any period, then LEO Pharma shall pay such payment amount (including interest thereon calculated in accordance with the last sentence of Section 7.5 from the date such amounts were payable) within thirty (30) days after the date Portal delivers to LEO Pharma such accountant's written report so concluding, unless LEO Pharma notifies Portal of any dispute regarding the audit and commences proceedings under Section 3.2(d) within thirty (30) days after delivery of the accountant's report (in which case the payment shall be delayed until conclusion of the proceeding). Such auditors shall not be paid on a contingency basis. Any Information received by Portal pursuant to this Section 9.3 shall be deemed to be Confidential Information of LEO Pharma.

9.4 **Survival.** This Article 9 shall survive any termination or expiration of this Agreement for a period of five (5) years following the final payment made by LEO Pharma hereunder, or longer if required by Applicable Law.

10. INVENTIONS, KNOW-HOW AND PATENTS

10.1 **Existing Intellectual Property.** Other than as expressly provided in this Agreement, neither Party grants any right, title, or interest in any Patent rights, Information, or other Intellectual Property right Controlled by such Party to the other Party.

10.2 **Ownership of Inventions.**

(a) Ownership of inventions created, developed, conceived or reduced to practice during and in the course of the Parties' performance under the Agreement, and related patent rights (**"Inventions"**) shall be determined in accordance with the United States rules of inventorship, except as otherwise set forth in this Section 10.2(a), below. For clarity, except as set forth in this Section 10.2(a), each Party shall have an undivided interest in and to (i) any Inventions, created, developed, conceived, or reduced to practice jointly by employees or independent contractors of both Parties (**"Joint Inventions"**) and (ii) any other Intellectual Property created, developed, conceived, or reduced to practice jointly by employees or independent contractors of both Parties (together with Joint Inventions, **"Joint Intellectual Property"**), in each case without a duty of accounting to the other Party and without an obligation to obtain consent of the other Party to grant licenses thereunder in countries in which such duty or obligation would otherwise apply. Notwithstanding the foregoing:

(i) Subject to Section 10.3(a)(i), Portal shall solely own all Inventions (including Joint Inventions) and all other Intellectual Property (including Joint Intellectual Property) created or developed in the course of the Parties' performance under the Agreement relating to the Device and/or Cartridge, to methods of using or Manufacturing the Device and/or Cartridge, and/or to the Portal Platform Technology and/or any Improvements to any of the foregoing, whether made by employees, independent contractors or Agents of either Party or jointly by employees, independent contractors or Agents of both Parties. Such Inventions and Patents and Patent Applications claiming such Inventions and other Intellectual Property and Improvements are included in the Portal Patent Rights and Portal Know-How, as applicable, and licensed to LEO Pharma pursuant to Section 2.2.

(ii) Subject to Section 10.3(a)(ii), LEO Pharma shall solely own all Inventions (including Joint Inventions) and all other Intellectual Property (including Joint Intellectual Property) created or developed in the course of the Parties' performance under this Agreement relating to LEO Pharma's Drug or to methods of using or Manufacturing LEO Pharma's Drug, including methods of treatment using LEO Pharma's Drug and/or any Improvements to any of the foregoing, whether made by employees, independent contractors or Agents of either Party or jointly by employees, independent contractors or Agents of both Parties. Such Inventions and Patents and Patent Applications claiming such Inventions and such other Intellectual Property and Improvements are subject to the covenant not to sue granted by LEO Pharma to Portal under Section 2.6.

(b) Assignment and Perfection of Interests. Without additional consideration except as otherwise provided for in this Section 10.2(b), each Party hereby assigns to the other Party such of its right, title and interest in and to any Inventions, Patent rights claiming them, and all other Intellectual Property rights therein, including enforcement rights, and shall require its Sublicensees, Subcontractors, Affiliates, independent contractors, employees or Agents to so assign to the other Party such of their right, title and interest in and to the foregoing, as is necessary to effectuate the allocation of right, title and interest in and to Inventions, other Intellectual Property and Improvements solely as set forth in Section 10.2(a). Each Party shall, and shall cause its Sublicensees, Subcontractors, Affiliates, independent contractors, employees

and Agents to, cooperate with the other Party and take all reasonable additional actions and execute such agreements, instruments and documents as may be reasonably required to perfect the other Party's right, title and interest in and to Inventions, Patent rights and other Intellectual Property rights as such other Party has pursuant to Section 10.2(a). Each Party shall also include provisions in its relevant agreements with Third Parties that effect the intent of this Section 10.2(b).

10.3 **Patent Prosecution and Maintenance.**

(a) Portal shall file and prosecute Patent Applications and maintain Patents in a manner consistent with optimizing Patent protection on Inventions and other inventions Controlled by Portal that are disclosed and/or claimed in the Portal Patent Rights. Portal shall cause its patent counsel to confer no less frequently than once each Calendar Quarter regarding the status of all such Patent Applications and Patents for which it is responsible under this Section 10.3, and whether and in which countries foreign counterparts of such Patent Applications and Patents shall be filed. The Parties shall set the location, date, time and type of meeting (either in person, by teleconference, or by videoconference) so as to be mutually agreeable to the patent counsel of each Party.

(i) Portal shall bear the full costs and expense of and be responsible for filing, prosecuting and maintaining Patents and Patent Applications claiming inventions it Controls as of the Effective Date and those it Controls that arise outside the Parties' performance pursuant to this Agreement, and Patents and Patent Applications on Inventions it solely owns under the Agreement. If Portal does not wish to file, prosecute or maintain any such Patent Applications or Patents that relate to the Device included in the Product, a component of the Device included in the Product, a method of using or manufacturing the Device included in the Product, or a method of using or manufacturing the Product in any country, Portal shall give LEO Pharma reasonable written notice to such effect and shall grant LEO Pharma any necessary authority to file, prosecute and maintain such Patent Applications or maintain such a Patent in LEO Pharma's own name and at LEO Pharma's sole expense. In such event, Portal shall assign its entire right, title and interest in and to such Patent Applications or Patents in that country to LEO Pharma. Portal shall give LEO Pharma reasonable written notice of the countries and regions in which it will file such Patent Applications in order to permit LEO Pharma reasonable time to file such Patent Applications in any country in which Portal will not be filing. If LEO Pharma wishes to file such Patent Applications in any additional countries, Portal shall provide LEO Pharma with copies of any documents necessary to conduct such filings and shall grant LEO Pharma any necessary authority to file, prosecute and maintain such Patent Applications in LEO Pharma's own name and at LEO Pharma's sole expense. In such event, Portal shall assign its entire right, title and interest in and to such Patent Applications in that country to LEO Pharma. LEO Pharma shall bear the full costs and expense of and be solely responsible for prosecuting, maintaining, enforcing and defending any Patent or Patent Application assigned to LEO Pharma under this Section 10.3(a)(i). In the event that LEO Pharma chooses not to prosecute, maintain, enforce or defend any such Patents or Patent Applications, Portal will have the option to do so at its sole cost and expense. Notwithstanding the foregoing, LEO Pharma's rights to step in under this Section 10.3(a)(i) shall be subject to limitations imposed in any license agreement with a Third Party existing as of the Effective Date relating to the Patents and Patent Applications to be

filed, prosecuted, and/or maintained.

(ii) As between the Parties, LEO Pharma shall bear the full costs and expense of and be responsible for filing, prosecuting and maintaining Patents and Patent Applications on Inventions it solely owns under the Agreement, in its discretion.

(iii) For any Joint Inventions and other Joint Intellectual Property that are jointly owned by the Parties, the Parties shall discuss in good faith and decide whether a joint patent application or similar protection (**"Joint Patent Rights"**) or other application for registration will be filed for such Joint Inventions or other Joint Intellectual Property, respectively, and if so, negotiate an agreement governing joint ownership, enforcement, protection and licensing of such rights to such Joint Inventions and other Joint Intellectual Property, including allocation of associated costs and expenses. During the Term, and at all times subject to Article 14 of this Agreement, except to the extent necessary to perform under this Agreement, to avoid loss of Patent Rights as a result of premature public disclosure of patent able information, neither Party may use or disclose any Joint Invention without the prior written consent of the other Party.

(b) Each Party shall promptly disclose, and shall cause its Sublicensees, Subcontractors and Affiliates to disclose, to the other in writing all Inventions and Intellectual Property rights arising from the joint activities of the Parties or their respective Agents, contractors, Affiliates and sublicensees during and in connection with the performance of the activities conducted pursuant to this Agreement.

10.4 **Third Party Licenses.**

(a) If either Party reasonably determines that certain Third Party Intellectual Property rights are necessary for the Development or Commercialization of the Product, where such Third Party Intellectual Property rights are necessary solely due to the inclusion of LEO Pharma's Drug in the Product, LEO Pharma may in its discretion and at its expense obtain a license to such Third Party Intellectual Property, with the right to sublicense, in order to permit both Parties to conduct their obligations under the Agreement. The terms and conditions involved in obtaining such rights shall be determined at LEO Pharma's sole discretion. If LEO Pharma elects not to obtain rights to such Third Party Intellectual Property, or is unsuccessful in obtaining such rights, then Portal shall have the right (but not the obligation) to negotiate and obtain rights from such Third Party at its sole discretion and expense. If either Party reasonably determines that certain Third Party Intellectual Property rights are necessary for the Development or Commercialization of the Product, where such Third Party Intellectual Property rights are necessary solely due to the inclusion of the Device, a component thereof, or the Portal Platform Technology in the Product, Portal may in its discretion and at its expense obtain a license to such Third Party Intellectual Property, with the right to sublicense, in order to permit both Parties to conduct their obligations under the Agreement. The terms and conditions involved in obtaining such rights shall be determined at Portal's sole discretion. If Portal elects not to obtain rights to such Third Party Intellectual Property, or is unsuccessful in obtaining such rights, then LEO Pharma shall have the right (but not the obligation) to negotiate and obtain rights from such Third Party at its sole discretion and expense. Notwithstanding the foregoing, each Party's rights to step in under this Section 10.4(a) shall be subject to limitations imposed in any license

agreement with the other Party and any Third Party existing as of the Effective Date relating to the Third Party Intellectual Property rights to be obtained. If either Party reasonably determines that certain Third Party Intellectual Property rights are necessary for the Development or Commercialization of the Product, where such Third Party Intellectual Property rights are required for reasons not solely based on the inclusion of LEO Pharma's Drug, the Device, a component thereof, or the Portal Platform Technology in the Product, the Parties may jointly obtain the requisite rights to such Third Party Intellectual Property as mutually agreed by the Parties in writing, including with respect to allocation of associated costs. The terms and conditions involved in obtaining such rights shall be mutually agreed upon by both Parties.

(b) If the Parties disagree on whether rights in Third Party Intellectual Property are reasonably necessary for the Development or Commercialization of the Product, the issue shall be escalated to the Authorized Representatives; provided that neither Party shall be required to negotiate or purchase any license to any Third Party Intellectual Property.

10.5 **Infringement by Third Parties.** Subject to Section 10.3(a)(ii), as between the Parties, LEO Pharma shall have the exclusive right, but not the obligation, at its own cost and expense, to enforce Patents throughout the Territory that claim the composition of matter of, methods of making, or methods of using LEO Pharma's Drug, which right includes the right to control and settle the litigation. Subject to Section 10.3(a)(i), Portal shall bear the full costs and expenses of enforcing, and shall have the first right to enforce, Patents throughout the Territory that claim the Device, methods of using or manufacturing the Device, or to the Portal Platform Technology, which right includes the right to control and settle the litigation (subject to the last sentence of this Section 10.5). If Portal does not initiate an enforcement action within ninety (90) days after the Parties first learn of such infringement, LEO Pharma shall have the right to enforce such Patents against infringers to the extent such infringement relates to products competitive with the Product in the Field. All of the costs and expenses of both Parties incurred in connection with such proceedings shall be borne by the Party bringing such action, and any recoveries shall be awarded to the enforcing Party. For Portal Patent Rights and Patents Controlled by LEO Pharma and/or its Affiliates relating to a combination of LEO Pharma's Drug and the Device (in each case, including Joint Patent Rights), the Parties shall jointly enforce such Patents throughout the Territory (if and solely to the extent authorized to do so under any applicable agreement with any Third Party) and share the costs associated with such enforcement and any recoveries associated therewith as follows: LEO Pharma shall bear or receive fifty percent (50%) of such costs or recovery, as applicable, and Portal shall bear or receive fifty percent (50%) of such costs or recovery, as applicable. If one Party chooses not to participate in enforcement of Patents relating to a combination of LEO Pharma's Drug and the Device, the other Party shall have the right to enforce such Patents (provided all of the costs and expenses of both Parties incurred in connection with such enforcement shall be borne by the enforcing Party), including the right to settle such litigation (subject to the last sentence of this Section 10.5) at its sole expense and to keep all recoveries associated therewith. If, in any enforcement action taken pursuant to this Section 10.5, the enforcing Party determines that the other Party is an indispensable party to such action, the other Party hereby consents to be joined in such action and, in such event, the other Party shall have the right to be represented in such action using counsel of its own choice at the enforcing Party's expense. Notwithstanding the foregoing, each Party's enforcement rights under this Section 10.5 shall be subject to limitations imposed in any license agreement with a Third Party relating to the Patent to be enforced. The joint consent of LEO Pharma and Portal (which consent

shall not be unreasonably withheld or delayed) shall be required of any settlement, consent judgment or other voluntary final disposition of a suit under this Section 10.5 that could adversely affect the other Party's interest.

10.6 **Infringement Not Related to the Product.** Portal shall retain any and all rights to pursue an action against, and control all proceedings relating to, an infringement by a Third Party of the Portal Patent Rights or Portal Know-How that is not related to the Product. LEO Pharma shall retain any and all rights to pursue an action against, and control all proceedings relating to, an infringement by a Third Party of a Patent relating to an Invention solely owned or Controlled by LEO Pharma under the Agreement that is not related to the Product.

10.7 **Further Actions.** Each Party shall cooperate with the other Party to execute all documents and take all reasonable actions to effect the intent of this Article 10.

10.8 **M.I.T. Patents.** M.I.T. retains certain rights to prosecute and enforce certain Patents and Patent Applications licensed to Portal under the M.I.T. Agreement.

11. REPRESENTATIONS AND WARRANTIES

11.1 **The Parties' Representations and Warranties.** Portal and LEO Pharma (each a **"Representing Party"**) each hereby represents and warrants to each other, as of the Effective Date, as set forth below:

(a) To the best of such Representing Party's knowledge, all of its employees, officers, contractors and consultants have executed agreements requiring assignment to such Representing Party of all Inventions and other Intellectual Property (including Improvements) created, developed, conceived, reduced to practice or otherwise discovered by or on behalf of such Party, its Affiliates, Subcontractors or Sublicensees in the course of activities performed in connection with the Device, Cartridge, Product or LEO Pharma's Drug, as applicable, and obligating each such employee, officer, contractor and consultant to maintain as confidential the Confidential Information of such Representing Party.

(b) It has the power, authority and legal right, and is free, to enter into this Agreement and, in so doing, will not violate any other agreement to which it is a party as of the Effective Date. Moreover, during the Term of this Agreement, it shall not enter into any agreement with any Third Party that will conflict with the rights granted to another Representing Party under this Agreement. This Agreement has been duly executed and delivered on behalf of such Representing Party and, assuming due execution by the other Party, constitutes a legal, valid and binding obligation of such Representing Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

(c) It has taken all corporate action necessary to authorize the execution and delivery of this Agreement.

(d) Neither it, nor any of its employees, officers, subcontractors or

consultants who have rendered or will render services relating to the Project or the Product: (i) has ever been debarred or is subject or debarment or convicted of a crime for which an entity or person could be debarred under 21 U.S.C. Section 335a, or (ii) has ever been under indictment for a crime for which a person or entity could be debarred under said Section 335a. If during the Term, a Representing Party has reason to believe that it or any of its employees, officers, Subcontractors, Sublicensees or consultants rendering services relating to the Project or the Product: (x) is or will be debarred or convicted of a crime under 21 U.S.C. Section 335a, or (y) is or will be under indictment under said Section 335a, then such Representing Party shall immediately notify the other Representing Parties of same in writing.

(e) All necessary consents, approvals and authorizations of all Regulatory Authorities and other Third Parties required to be obtained by such Representing Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

(f) The execution and delivery of this Agreement and the performance of such Representing Party's obligations hereunder (i) do not conflict with or violate any requirement of Applicable Law or any provision of the articles of incorporation, bylaws, limited partnership agreement or any similar instrument of such Representing Party, as applicable, in any material way, and (ii) do not conflict with, violate, or breach or constitute a default or require any consent under, any Applicable Law or any contractual obligation or court or administrative order by which such Representing Party is bound.

11.2 **Additional Representations and Warranties of LEO Pharma.** LEO Pharma hereby represents and warrants to Portal, as of the Effective Date, that LEO Pharma (a) is a corporation duly organized and subsisting under the laws of its jurisdiction of organization, and (b) has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.

11.3 **Additional Representations and Warranties of Portal.** Portal hereby represents and warrants and covenants to LEO Pharma, as of the Effective Date, as set forth below:

(a) Portal is a corporation duly organized, validly existing and subsisting under the laws of the State of Delaware, and has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as is contemplated to be conducted by this Agreement.

(b) Neither Portal nor any of its Affiliates, nor to Portal's Knowledge M.I.T., have assigned, transferred, conveyed or otherwise encumbered in the Field, or will assign, transfer, convey or otherwise encumber in the Field, any right, title or interest in or to the Portal Patent Rights, the Portal Know-How, the Portal Platform Technology or the Portal Trademarks.

(c) There are no judgments or settlements against Portal, or to Portal's Knowledge, M.I.T., or amounts owed by Portal (other than amounts owed in the ordinary course of business), or to Portal's Knowledge, M.I.T., with respect to the Portal Patent Rights, the Portal Know-How, the Portal Platform Technology or the Portal Trademarks, except with respect to the

M.I.T. Agreement.

(d) Portal is in compliance in all material respects with the M.I.T. Agreement and any other agreement between Portal and a Third Party relating to the practice of the Portal Patent Rights in the Field or the use or exercise of other rights in the Portal Know-How, the Portal Platform Technology or the Portal Trademarks.

(e) All Patents and Patent Applications owned by Portal as of the Effective Date that claim a product, method, apparatus, material, manufacturing process or other technology necessary to develop, make, use, sell, offer for sale, import or export LEO Pharma's Drug, the Device, or Product in the Field and in the Territory, all Portal Know-How, the Portal Technology Platform and the Portal Trademarks are Controlled by Portal as of the Effective Date.

(f) Neither Portal nor, to Portal's Knowledge, M.I.T., has received any written (or to Portal's Knowledge, oral) claim or demand alleging that any of the Portal Patents are invalid or unenforceable or challenging ownership or registration of, or right to exercise any rights under, any Portal Patents, Portal Know-How, Portal Platform Technology or Portal Trademarks. To Portal's Knowledge, no patent application or registration within the Portal Patents is the subject of any pending interference, opposition, cancellation, or patent protest pursuant to 37 C.F.R. §1.291 or any similar provisions under Applicable Law.

(g) Portal has the right to grant the licenses and sublicenses granted to LEO Pharma under this Agreement.

(h) To Portal's knowledge, LEO Pharma's exercise of the license rights granted to it under this Agreement, and the Development and Commercialization of the Device, Cartridge, or Product as contemplated by this Agreement, do not and will not infringe, misappropriate or otherwise violate any rights, including any Intellectual Property rights of any Third Party. There is no pending or threatened litigation nor has Portal received any written communications alleging that it has violated or would violate, through the Development, Manufacture, import and/or sale or other Commercialization of the Device, Cartridge or Product hereunder, or by conducting its obligations under the Project as currently proposed under this Agreement, any rights including Intellectual Property rights of any Third Party.

(i) To Portal's Knowledge, no Person is infringing or otherwise violating, or threatening to infringe or otherwise violate, any of the Portal Patents, Portal Know-How, Portal Platform Technology or Portal Trademarks in the Field.

(j) To Portal's Knowledge, no Portal Patent, Portal Know-How, Portal Platform Technology or Portal Trademark is subject to any lien or other encumbrance in favor of any Third Party that conflicts with the rights and licenses granted to LEO Pharma under this Agreement.

(k) To Portal's Knowledge, there is no pending product liability litigation in relation to any Device, Cartridge or Product.

(l) Portal has made available to LEO Pharma true and correct copies of the M.I.T. Agreement and has made available or offered to make available to LEO Pharma all

material regulatory documentation for the Territory with respect to the Device, Cartridges and Product that are in Portal's possession or Control as of the Effective Date, and will make available to LEO Pharma from and after the Effective Date all amendments to the M.I.T. Agreement and other material regulatory documentation.

(m) Portal has disclosed to LEO Pharma and made available or offered to make available to LEO Pharma for review all material pre-clinical and clinical data for the Device, Cartridge and Product, and all other material information (including relevant correspondence with Regulatory Authorities) relating directly to the Development of the Device, Cartridge or Product, in each case that would be material in order to assess the safety and efficacy of the Device, Cartridge and Product.

(n) The Portal Patents, Portal Know-How and Portal Platform Technology constitute all Intellectual Property or proprietary rights Controlled by Portal or any of its Affiliates that would, absent the licenses granted to LEO Pharma hereunder, be infringed or otherwise violated by the Development or Commercialization by LEO Pharma of the Product in the Field in the Territory.

(o) To Portal's Knowledge, no representation or warranty by Portal in this Agreement and no written information, statement, report or document, furnished to LEO Pharma or its Affiliates or its or their representatives by or on behalf of Portal in connection with LEO Pharma's determination to enter into this Agreement (i) contains any untrue statement of a material fact, or omits to state a material fact necessary to make the statements contained therein, in light of the circumstances in which they are made, not misleading or (ii) omits to state a material fact necessary in order to provide LEO Pharma with complete and accurate information, to Portal's Knowledge, as to the development prospects of the Product, including the probability and timing of achieving the milestones set forth in the Development Plan, based on the facts and circumstances known as of the Effective Date; and (iii) to Portal's Knowledge, based on the facts and circumstances known as of the Effective Date, there is no event or circumstance that Portal has not disclosed to LEO Pharma or its Affiliates that could reasonably be expected to have a material adverse effect on (A) the Product, (B) the licenses granted pursuant to this Agreement, (C) Portal's ability to consummate the transactions and fulfill its obligations contemplated by this Agreement on a timely basis or (D) the ability for the Product to be Commercialized in the Territory.

12. COVENANTS OF THE PARTIES

12.1 **Non-Solicitation.** During the period beginning on the Effective Date and continuing until the date that is two (2) years after the earlier of (i) the expiration of the Term or (ii) termination of this Agreement in its entirety pursuant to Article 17 (the **"Restricted Period"**), neither Party shall, and shall cause its Affiliates not to, without the express written consent of the other Party, directly or indirectly, recruit, solicit for employment or induce any employee of the other Party to terminate his or her employment with such other Party. The foregoing provision shall not, however, restrict either Party or its Affiliates from advertising employment opportunities in any manner that does not directly target any employee of the other Party or its Affiliates or from hiring any persons who respond to such generalized public advertisements.

12.2 **Transition of Manufacturing Responsibilities.** If LEO Pharma, in its

reasonable discretion, determines that there is a significant risk that Portal or its designated Third Party manufacturer will not be able to perform for a material amount of time any of its material obligations hereunder that are due to be performed in the next six (6) months, Portal shall as soon as reasonably practicable, and in no event later than ten (10) Business Days after receipt of written notification from LEO Pharma thereof, provide to LEO Pharma a remedy plan that is reasonably acceptable to LEO Pharma (each such plan, a **"Remedy Plan"**). The Remedy Plan shall describe how and when Portal plans to ensure performance of its and any designated Third Party manufacturer's obligations hereunder and shall reflect the importance and urgency of such timely and unhindered performance. Portal shall allocate resources and capacities accordingly in order to keep the timeline agreed, and in case of delay, seek to minimize and/or reduce the effects thereof. Portal shall promptly notify LEO Pharma in writing in case of any anticipated significant delay or if there are circumstances that can have an impact on agreed timelines. If Portal does not deliver a Remedy Plan before the aforementioned deadline, or if LEO Pharma, following receipt of a Remedy Plan and after Portal having had at least sixty (60) days to implement the Remedy Plan, in its reasonable discretion, determines that Portal or its designated Third Party manufacturer will not be able to perform for a material amount of time any of its material obligations hereunder that are due to be performed in the next six (6) months, then Portal upon LEO Pharma's request shall effect a transfer to LEO Pharma or its designee (which designee may be an Affiliate of LEO Pharma or, subject to Portal's consent not to be unreasonably withheld, a Third Party manufacturer) all Information, materials and other technology transfer and assistance to enable the Manufacture, and solely to facilitate implementation of the Manufacture, of Devices and/or Cartridges, as applicable, at facilities designated by LEO Pharma. For purposes of this Section 12.2, ninety (90) days shall be considered a material amount of time. Portal shall provide all reasonable assistance requested by LEO Pharma to enable LEO Pharma (or its Affiliate or designated Third Party manufacturer, as applicable) to implement Manufacturing of Devices and Cartridges (the **"Manufacturing Process"**) at the facilities designated by LEO Pharma. If reasonably requested by LEO Pharma, such assistance shall include facilitating the entering into of agreements with applicable Third Party suppliers relating to the Device and/or Cartridge. Without limitation to the foregoing, in connection with such technology transfer, Portal shall cause all appropriate employees and representatives of Portal and its Affiliates to meet with employees or representatives of LEO Pharma (or its Affiliate or designated Third Party manufacturer, as applicable) at the applicable manufacturing facility at mutually convenient times to assist with the working up and use of the Manufacturing Process and with training of personnel of LEO Pharma (or its Affiliate or designated Third Party manufacturer, as applicable) to the extent reasonably necessary or useful to enable LEO Pharma (or its Affiliate or designated Third Party manufacturer, as applicable) to use and practice the Manufacturing Process. For the avoidance of doubt, LEO Pharma's exercise of its rights under this Section 12.2 shall not constitute termination of this Agreement or affect LEO Pharma's rights under Section 17 of this Agreement.

12.3 **Compliance with Applicable Laws.** Each Party shall comply with all Applicable Laws in performing its obligations and exercising its rights hereunder. Nothing in this Agreement shall be deemed to permit either Party to export, re-export or otherwise transfer any Information transferred hereunder or Product manufactured therefrom without complying with Applicable Law.

12.4 **Privacy and Data Protection Matters.** All Data, including all such de-identified or aggregated information, shall be and remain the property of LEO Pharma, regardless

of whether it has been processed by Portal or is in Portal's possession or control. Portal shall not use any Data for any purpose other than to perform its obligations under this Agreement, to research, develop and improve the Device and/or Portal Platform Technology, or as otherwise directed in writing by LEO Pharma. Portal shall not, and shall cause its Affiliates and Subcontractors not to, sell, rent, assign, lease or otherwise dispose of any Data to any Third Party or commercially exploit any Data, except indirectly via the use of such Data to research, develop and improve the Device and/or Portal Platform Technology. Following the Effective Date and at the direction of the JDC after further discussions regarding the nature and features of the Product Interface, the Parties shall negotiate and enter into a Data Processing Agreement consistent with the requirements set forth therefor in Exhibit 12.4.

12.5 **Additional Covenants.** Each Party hereby covenants to the other Party that, during the Term:

(a) such Party shall not enter into any agreement with, or grant any right or license to, a Third Party that conflicts with the rights granted to the other Party under this Agreement; and

(b) all employees and independent contractors of such Party and/or its Affiliates, Subcontractors and Sublicensees, and any other Persons who have conceived, reduced to practice or otherwise discovered for or on behalf of such Party or its Affiliates, Subcontractors or Sublicensees in connection with the Product shall be obligated to assign to such Party any and all Inventions (including improvements) conceived, reduced to practice or otherwise discovered by or on behalf of such Party, its Affiliates, Subcontractors or Sublicensees in the course of activities performed under or contemplated by this Agreement and to maintain as confidential any and all Confidential Information.

13. MUTUAL INDEMNIFICATION AND INSURANCE

13.1 **Portal's Right to Indemnification.** LEO Pharma shall indemnify, defend and hold harmless each of Portal and its Affiliates and their respective successors, assigns, directors, officers, employees, Subcontractors and Agents, from and against any and all liabilities, damages, losses, settlements, penalties, fines, costs and expenses, including reasonable attorneys' fees and litigation costs (any of the foregoing to be referred to herein as **"Damages"**) of whatever kind or nature (but not including taxes) arising from any Third Party demand, investigation, claim, action or suit in the Territory to the extent based on (i) any act, whether of omission or commission, by LEO Pharma (or its Affiliates, Sublicensees, Subcontractors or any of their respective directors, officers, Agents, employees or contractors) with respect to its failure to properly discharge or perform its areas of responsibility under this Agreement, including, the supply of LEO Pharma's Drug for Commercial purposes (including any defect or alleged defect in LEO Pharma's Drug provided pursuant to this Agreement or any injury or death of any person arising out of or related to LEO Pharma's Drug provided pursuant to this Agreement), packaging and distribution of the Product for Commercial purposes, the conduct of any Clinical Trial by LEO Pharma, and the Exploitation of the Product, except in each case for those types of Damages for which Portal has an obligation to indemnify LEO Pharma and its Affiliates pursuant to Section 13.2; (ii) the gross negligence or willful or intentional misconduct of LEO Pharma, its Affiliates or any of its Sublicensees or their respective directors, officers, Agents, employees or contractors under this

Agreement; (iii) a material breach by LEO Pharma of any term of this Agreement, (iv) a material breach by LEO Pharma of any obligation, representation, warranty or covenant hereunder; or (v) a violation of Applicable Law in the performance of its duties under this Agreement by LEO Pharma, its Affiliates or any of its Sublicensees or their respective directors, officers, Agents, employees or contractors, in each case except to the extent caused by (a) the gross negligence or willful intentional misconduct of Portal, its Affiliates, or Sublicensees, or any of their respective directors, officers, Agents, contractors or employees under this Agreement; (b) material breach by Portal of any term of this Agreement; (c) the material breach by Portal of any obligation, representation, covenant or warranty hereunder; or (d) any violation of Applicable Law in the performance of its duties under this Agreement by Portal, its Affiliates, or Sublicensees, or any of their respective directors, officers, Agents, contractors or employees (except to the extent such violation is caused by LEO Pharma).

13.2 **LEO Pharma's Right to Indemnification.** Portal shall indemnify, defend and hold harmless each of LEO Pharma and its Affiliates and their respective successors, assigns, directors, officers, employees, Sublicensees, Subcontractors and Agents, from and against any and all Damages of whatever kind or nature (but not including taxes) arising from any Third Party demand, investigation, claim, action or suit in the Territory to the extent based on (i) any act, whether of omission or commission, by Portal (or its Affiliates, Subcontractors or any of their respective directors, officers, Agents, employees or contractors) with respect to its failure to properly discharge or perform its areas of responsibility under this Agreement, including, the supply of the Device or any Cartridge (including any defect or alleged defect in the Device or any Cartridge provided pursuant to this Agreement or any injury or death of any person arising out of or related to any Device provided pursuant to this Agreement), except for those types of Damages for which LEO Pharma has an obligation to indemnify Portal and its Affiliates pursuant to Section 13.1; (ii) any allegation that the Device, Cartridge or LEO Pharma's exercise of the rights licensed to it under this Agreement (including with respect to the Portal Patents, Portal Know-How, Portal Platform Technology or Portal Trademarks) or Exploitation of Products infringes, misappropriates or otherwise violates any Intellectual Property or other proprietary right of any Person; (iii) the gross negligence or willful or intentional misconduct of Portal, its Affiliates or any of its Subcontractors or any of their respective directors, officers, Agents, employees or contractors under this Agreement; (iv) a material breach by Portal of any term of this Agreement; or (v) a material breach by Portal of any obligation, representation, warranty or covenant hereunder; or (vi) a violation of Applicable Law in the performance of its duties under this Agreement by Portal, its Affiliates or any of its Subcontractors or their respective directors, officers, Agents, employees or contractors, in each case except to the extent caused by (a) the gross negligence or willful intentional misconduct of LEO Pharma, its Affiliates, Sublicensees or Subcontractors, or any of their respective directors, officers, Agents, contractors or employees under this Agreement; (b) material breach by LEO Pharma of any term of this Agreement; (c) the material breach by LEO Pharma of any obligation, representation, covenant or warranty hereunder; or (d) any violation of Applicable Law in the performance of its duties under this Agreement by LEO Pharma, its Affiliates, Sublicensees, or Subcontractors, or any of their respective directors, officers, Agents, contractors or employees (except to the extent such violation is caused by Portal).

13.3 **Process for Indemnification.** A Party's obligation to defend, indemnify and hold harmless the other Party under this Article 13 shall be conditioned upon the following:

(a) A Party seeking indemnification under this Article 13 (the **"Indemnified Party"**) shall give prompt written notice of the claim to the other Party (the **"Indemnifying Party"**).

(b) Each Party shall furnish promptly to the other, copies of all papers and official documents received in respect of any Damages. The Indemnified Party shall cooperate as requested by the Indemnifying Party in the defense against any Damages.

(c) With respect to any Damages relating solely to the payment of money damages and which will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affecting the business of the Indemnified Party in any manner, and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party under this Article 13, the Indemnifying Party shall have the sole right to defend, settle or otherwise dispose of such Damages, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate.

(d) With respect to Damages relating to all other matters, the Indemnifying Party shall have the sole right to control the defense of such matter, provided that the Indemnifying Party shall obtain the written consent of the Indemnified Party, which consent shall not be unreasonably withheld or delayed, prior to ceasing to defend, settling or otherwise disposing of any Damages if as a result thereof (i) the Indemnified Party would become subject to injunctive or other equitable relief or any remedy other than the payment of money by the Indemnifying Party or (ii) the business of the Indemnified Party would be adversely affected.

(e) The Indemnifying Party shall not be liable for any settlement or other disposition of Damages by the Indemnified Party which is reached without the written consent of the Indemnifying Party, which consent shall not be unreasonably withheld, conditioned or delayed, it being understood that if such consent is withheld, the Indemnifying Party will be responsible for the amount of damages or increased costs and expenses attributable to such failure to give consent.

(f) The Indemnified Party shall have the right to participate in the defense of the claim using counsel of its choosing, at its own expense, unless the Indemnifying Party has failed to assume the defense and employ counsel (in which case the Indemnified Party shall control the defense) or the interest of the Indemnified Party and the Indemnifying Party with respect to such claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles (in which case, the Indemnified Party shall control its defense).

13.4 **Insurance.**

(a) During the Term of this Agreement and for seven (7) years thereafter, LEO Pharma shall either (i) maintain, at its sole expense, clinical trial and product liability insurance relating to the Product that is comparable in type and amount to the insurance customarily maintained by LEO Pharma with respect to similar prescription pharmaceutical products that are marketed, distributed and sold in the Territory, or (ii) self-insure for such risks.

(b) During the Term of this Agreement and for seven (7) years

thereafter, Portal shall maintain, at its sole expense, (i) commercial general liability insurance, including product liability insurance, with a limit of not less than $5,000,000 per occurrence and $10,000,000 in the annual aggregate, and (ii) cyber-liability insurance in a minimum amount of $5,000,000 and covering, without limitation, any breaches by Portal of its obligations or representations and warranties under the Data Processing Agreement to be entered into pursuant to Section 12.4, violations of privacy or security laws, security breaches (and all related costs, including those related to investigation, notification and third party action), wrongful disclosure, negligent handling of confidential information and related costs (including, costs of investigation, notification, credit monitoring, regulatory investigations and enforcement actions and other lawsuits); provided, however, that until the initiation of the first Clinical Trial, Portal shall only be required to maintain, at its sole expense, commercial general liability insurance with a limit of not less than $1,000,000 per occurrence and excess liability insurance with a limit of not less than $1,000,000 per occurrence. Such insurance shall be on a claims made basis with tail coverage and name LEO Pharma as an additional insured. A copy of such policies or certificates evidencing the policies shall be provided to LEO Pharma upon written request.

(c) It is understood that any insurance in place pursuant to this Section 13.4 shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 13. Each Party shall provide the other with written evidence of such insurance upon request. Each Party shall provide the other with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance or self-insurance that materially adversely affects the rights of the other Party hereunder.

13.5 **Right of Set-off**. The Parties shall have the right to withhold and set-off against any amount otherwise due to be paid under this Agreement any amount to which the Party may be entitled under this Article 13 or any or any other agreement entered into pursuant to or in connection with this Agreement.

14. CONFIDENTIALITY

14.1 **Confidentiality; Exceptions.** For the Term of this Agreement and for a period of five (5) years thereafter, each Party shall maintain in confidence and not disclose or use for any purpose other than as explicitly provided for in this Agreement any confidential and proprietary Information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise), of the other Party disclosed or provided to it by the other Party (either pursuant to this Agreement, or the Confidentiality Agreement entered into by Portal and LEO Pharma dated April 4, 2017) (together with all embodiments thereof, the **"Confidential Information"**). Confidential Information also includes, Information generated hereunder, and Information regarding Intellectual Property and confidential or proprietary Information of Third Parties. In addition, and notwithstanding the foregoing, if under Article 10 Information constituting Inventions and discoveries are to be owned by one Party, such Information shall be deemed to be Confidential Information of such Party, even if such Information is initially generated and disclosed by the other Party. The terms and conditions of this Agreement and the Confidentiality Agreement also shall be deemed Confidential Information of both Parties. LEO Pharma's Confidential Information shall include all information relating to LEO Pharma's business and marketing plans, product designs and decisions regarding the Product, including LEO Pharma's use of the System(s). Portal's Confidential Information shall include all information

relating to Portal's business and marketing plans, product designs and the Portal Platform Technology, and decisions regarding the Portal Platform Technology. Notwithstanding the foregoing, any Confidential Information that constitutes a trade secret shall not be subject to such five (5) year term, but shall continue to be subject to the obligations of confidentiality and non-use set forth in this Agreement for as long as such Confidential Information remains a trade secret under New York law. Notwithstanding the foregoing, Confidential Information shall not include that portion of Information or materials that the receiving Party can demonstrate by contemporaneous written records was (i) known to the general public at the time of its disclosure to the receiving Party, or thereafter became generally known to the general public, other than as a result of actions or omissions of the receiving Party or anyone to whom the receiving Party disclosed such Information; (ii) known by the receiving Party prior to the date of disclosure by the disclosing Party other than under an obligation of confidentiality at the time of disclosure by the other Party as evidenced by written records kept in the ordinary course of business or other documentary proof of actual use by the Party; (iii) disclosed to the receiving Party on an unrestricted basis from a source unrelated to the disclosing Party and not under a duty of confidentiality to the disclosing Party; or (iv) independently developed by the receiving Party by personnel that did not have access to or use of Confidential Information of the disclosing Party. Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or known to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation thereof are published or known to the general public or are in the rightful possession of the receiving Party.

14.2 **Degree of Care; Permitted Use.** Each Party shall take reasonable steps to maintain the confidentiality of the Confidential Information of the other Party, which steps shall be no less protective than those steps that such Party takes to protect its own Information and materials of a similar nature, but in no event less than a reasonable degree of care. Neither Party shall use or permit the use of any Confidential Information of the other Party except for the purposes of carrying out its obligations or exercising its rights under this Agreement or the Confidentiality Agreement, and neither Party shall copy any Confidential Information of the other Party except as may be reasonably useful or necessary for such purposes. All Confidential Information of a Party, including all copies and derivations thereof, is and shall remain the sole and exclusive property of the disclosing Party and subject to the restrictions provided for herein. Neither Party shall disclose any Confidential Information of the other Party other than to those of its and its Affiliates' directors, officers, employees, licensors, independent contractors, Sublicensees, Subcontractors, assignees, Agents and external advisors directly concerned with the carrying out of this Agreement, on a strictly applied "need to know" basis; provided, however, that such directors, officers, employees, licensors, independent contractors, Sublicensees, Subcontractors, assignees, Agents and external advisors are subject to confidentiality and non-use obligations at least as stringent as the confidentiality and non-use obligations provided for in this Article 14. Notwithstanding the foregoing, Portal shall not disclose any LEO Pharma Confidential Information to any Person employed by or associated with Sanofi-Aventis U.S. LLC or any of its Affiliates (including Sanofi Sunrise) or any other direct or indirect competitor of LEO Pharma, even if such Person is a director, external advisor or other permitted recipient of LEO Pharma's Confidential Information under this Article 14 and Portal shall cause any such Person to refrain from participating in any discussion or voting on any matter relating to this Agreement, the Product or the development, manufacture or commercialization of the Cartridge and/or the Device in the

Field and shall cause such Person to recuse such Person's self from the portion of any meeting of the board of directors of Portal relating thereto. Except to the extent expressly permitted under this Agreement, the receiving Party may not use Confidential Information of the other Party in applying for Patents or securing other Intellectual Property rights without first obtaining the written consent of, the other Party (which consent shall not be unreasonably withheld or delayed).

14.3 **Permitted Disclosures.** The obligations of Section 14.1, Section 14.2, and Section 15.1 shall not apply to the extent that the receiving Party is required to disclose Information pursuant to (a) an order of a court of competent jurisdiction, provided that the receiving Party provides the other Party with prompt written notice of such requirement so that such other Party may seek a protective order or other appropriate remedy, then the receiving Party may furnish only that portion of the Confidential Information that such Party is legally compelled to disclose, (b) Applicable Laws, (c) regulations or rules of a securities exchange; provided, however, that the Party shall offer reasonable cooperation in an attempt, as may be permitted and appropriate, to redact or seek confidential treatment of Confidential Information, (d) requirement of a governmental agency for purposes of obtaining approval to test or market the Product, including preparing and submitting regulatory materials and obtaining and maintaining Regulatory Approvals as permitted by this Agreement; provided, however, that reasonable measures shall be taken to assure confidential treatment of such Confidential Information, (e) disclosure of Information to a Patent or other office for the purposes of filing a Patent Application, copyright or trademark application as permitted in this Agreement, or (f) the exercise by each Party of its rights granted to it under this Agreement or its retained rights, including, the Exploitation of the Product, prosecuting or defending litigation, including responding to a subpoena in a Third Party litigation, and such Third Party agrees to confidentiality and non-use obligations at least as stringent as those specified for in this Article 14; provided that the receiving Party shall provide prior written notice thereof to the disclosing Party and sufficient opportunity for the disclosing Party to review and comment on such required disclosure and request confidential treatment thereof or a protective order therefor.

14.4 **Irreparable Injury.** The Parties acknowledge that either Party's breach of this Article 14 would cause the other Party irreparable injury for which it would not have an adequate remedy at law. In the event of a breach, the non-breaching Party may seek injunctive relief, whether preliminary or permanent, in addition to any other remedies it may have at law or in equity, without necessity of posting a bond.

14.5 **Return of Confidential Information.** Each Party shall return or destroy, at the other Party's instruction, all Confidential Information of the other Party in its possession upon termination or expiration of this Agreement, except any Confidential Information that is necessary to allow such Party to perform or enjoy any of its rights or obligations that expressly survive the termination or expiration of this Agreement.

15. PUBLICITY

15.1 **Public Disclosure.** The Parties agree that the initial public announcement of the execution of this Agreement shall be in the form of a mutually agreed upon press release that describes the nature and scope of the collaboration including its aggregate value. During the Term, LEO Pharma shall make all determinations in its sole discretion regarding any proposed

academic, scientific and medical publication or public presentation related to any Product or any activities conducted pursuant to this Agreement; provided, however, that prior to such publication or presentation, LEO Pharma shall provide Portal a reasonable opportunity to review and comment on such publication or presentation for the purposes of preserving Intellectual Property protection and determining whether any portion of the proposed publication or presentation containing the Confidential Information of Portal should be modified or deleted. Portal shall not make any academic, scientific and medical publication or public presentation related to any Product or any activities conducted pursuant to this Agreement without the prior written consent of LEO Pharma. Portal and LEO Pharma shall each comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publications.

15.2 **Statement Regarding Collaboration.** Subject to Applicable Law, any Information publicly disclosed by LEO Pharma relating to the Project for widespread public dissemination or release, whether in the form of press releases, technical publications or other public statements regarding the Project, shall include a prominent statement that the Project involves development and commercialization of products using Portal's proprietary delivery technology. Portal shall not use any LEO Pharma Trademark or any derivation of the LEO Pharma name without the advance express written consent of LEO Pharma, which consent may be granted or withheld in LEO Pharma's sole discretion.

16. TRADEMARKS

16.1 **Product Trademark; Use of Portal Trademark.** The Product, the Device, Product packaging (including, ampoules and vials), promotional materials, package inserts, and labeling shall bear one or more Trademark(s) chosen and owned by LEO Pharma. The Product, the Device, Product packaging (including, ampoules and vials), promotional materials, package inserts, and labeling shall also bear the Portal Trademark. Portal grants to LEO Pharma the right to use Portal's Trademarks solely to the extent necessary for LEO Pharma to exercise its rights and fulfill its obligations set forth in this Agreement. LEO Pharma shall not use any Portal Trademark outside the scope of this Agreement, and shall not knowingly take any action that would materially adversely affect the value of any Portal Trademark. Portal shall retain the right to monitor the quality of the Products on or with which the Portal Trademark is used solely to the extent necessary to maintain Portal's Trademark rights.

16.2 **Trademark Prosecution and Maintenance.** LEO Pharma shall bear the full costs and expense of and be responsible for filing, prosecuting and maintaining any Trademarks owned by LEO Pharma, in LEO Pharma's sole discretion. Portal shall bear the full costs and expense of and be responsible for filing, prosecuting, maintaining and defending any Trademarks owned by Portal, in Portal's sole discretion. If Portal does not wish to file, prosecute or maintain any applications for a Trademark or Trademarks that relate to the Device included in the Product, then Portal shall give LEO Pharma reasonable written notice to such effect and shall grant LEO Pharma any necessary authority to file, prosecute and maintain such application for a Trademark or maintain such a Trademark in LEO Pharma's own name and at LEO Pharma's sole expense. In such event, Portal shall assign its entire right, title and interest in and to such Trademark applications or Trademarks in that country to LEO Pharma. Portal shall give LEO Pharma reasonable written notice of the countries and regions in which it will file such Trademark applications in order to permit LEO Pharma reasonable time to file such Trademark applications

in any country in which Portal will not be filing. If LEO Pharma wishes to file such Trademark applications in any additional countries, Portal shall provide LEO Pharma with copies of any documents necessary to conduct such filings and shall grant LEO Pharma any necessary authority to file, prosecute and maintain such Trademark applications in LEO Pharma's own name and at LEO Pharma's sole expense. In such event, Portal shall assign its entire right, title and interest in and to such Trademark applications in that country to LEO Pharma. LEO Pharma shall bear the full costs and expense of and be solely responsible for prosecuting, maintaining, enforcing and defending any Trademark or Trademark application assigned to LEO Pharma under this Section 16.2. In the event that LEO Pharma chooses not to prosecute, maintain, enforce or defend any such Trademarks or Trademark applications, Portal will have the option to do so at its sole cost and expense. Notwithstanding the foregoing, LEO Pharma's rights to step in under this Section 16.2 shall be subject to limitations imposed in any license agreement with a Third Party existing as of the Effective Date relating to the Trademarks and Trademark applications to be filed, prosecuted, and/or maintained.

16.3 **Infringement Claims Against Third Parties.** The Parties agree to notify each other in writing of any known or suspected conflicting use of the other Party's Trademarks and the application for registration of Trademarks confusingly similar thereto, or of any known or suspected infringements or of unfair competition involving the other Party's Trademarks promptly after it acquires knowledge thereof. Each Party shall decide if and how it defends their Trademarks in the Territory at their own cost and expense.

17. TERM AND TERMINATION

17.1 **Term.** The term of this Agreement shall commence as of the Effective Date and, unless sooner terminated as specifically provided in this Agreement, shall continue in effect on a country-by-country and Product-by-Product basis, until the later of (a) the expiration of the last to expire Valid Claim in a Portal Patent covering the Product in such country, or (b) LEO Pharma's decision to manufacture on its own, or purchase the Devices or Cartridges from a Third Party (the **"Term"**).

17.2 **Termination by LEO Pharma.**

(a) LEO Pharma shall have the right to terminate the Agreement in its entirety, on a Product-by-Product basis, or on a county-by-country basis at will upon ninety (90) days' prior written notice, provided that LEO Pharma agrees that it will not exercise its termination rights pursuant to this Section 17.2(a) for at least one (1) year following the Effective Date of the Agreement. Notwithstanding the foregoing, in the event that LEO Pharma provides such a notice of termination, Portal may, in its sole discretion, reduce the applicable notice period set forth above by written notice to LEO Pharma.

(b) LEO Pharma shall have the right to terminate this Agreement upon written notice, at any time, if (i) the Parties fail to execute a Manufacturing and Supply Agreement within the timeframe required therefor under Section 8.2; (ii) upon termination of the Manufacturing and Supply Agreement for any reason; (iii) upon termination of the M.I.T. Agreement for any reason or if any of Portal's rights under the M.I.T. Agreement become non-exclusive for any reason; or (iv) upon termination of LEO Pharma's rights to made have made,

import, export, use, offer for sale, sell distribute or otherwise commercially exploit LEO Pharma's Drug for any reason.

(c) LEO Pharma shall have the right to terminate this Agreement upon written notice at any time upon any change of Control of Portal to Sanofi-Aventis U.S. LLC or any of its Affiliates (including Sanofi Sunrise) or any other direct or indirect competitor of LEO Pharma.

(d) LEO Pharma shall have the right to terminate this Agreement upon written notice at any time upon any breach of Portal's obligations under Article 14 with respect to Sanofi-Aventis U.S. LLC or any of its Affiliates (including Sanofi Sunrise).

17.3 **Termination for Material Breach.** If either Party believes the other is in material breach of a material obligation under this Agreement, it may give notice of such breach to the other Party, which other Party shall have sixty (60) days in which to remedy such breach, or thirty (30) days in the case of breach (whether material or not) of any payment obligation hereunder. Such sixty (60) day period shall be extended in the case of a breach not capable of being remedied in such sixty (60) day period so long as the breaching Party uses diligent efforts to remedy such breach and is pursuing a course of action that, if successful, will effect such a remedy. If such alleged breach is not remedied in the time period set forth above, the non-breaching Party shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement upon written notice to the other Party. In the event of a dispute regarding any payments due and owing hereunder, all undisputed amounts shall be paid when due, and the balance, if any, shall be paid promptly after settlement of the dispute, including any accrued interest thereon.

17.4 **Termination upon Insolvency.** Either Party may terminate this Agreement if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within forty-five (45) days after the filing thereof, or if the other Party shall propose or be a Party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.

17.5 **Effects of Termination.** Upon termination of this Agreement, the following terms and conditions shall apply:

(a) Upon termination by LEO Pharma under Section 17.2(b), 17.2(c), 17.2(d), 17.3 or 17.4, the license grants in Section 2.2(a) shall survive for such period of time and shall include all rights to Exploit the Product, the Product Interface and the Data (including for the avoidance of doubt the rights to make, have made, import and export the Device, Cartridge and Product and to develop, modify, create derivative works of, compile, host, operate, support and maintain the Product Interface), as is reasonably necessary for LEO Pharma and its Sublicensees to meet their contractual obligations to supply Product to customers existing as of the date of such termination and to complete Products in process and to sell and otherwise Exploit such Products

in process and any Products in inventory; however, in no event longer than three (3) years. Upon such termination by LEO Pharma under Section 17.2(c) or 17.2(d), such license grants shall be royalty-free, and upon such termination by LEO Pharma under Section 17.2(b), 17.3 or 17.4, such license grants shall require payment to Portal of royalty and milestone payments at fifty percent (50%) of the amounts/rates set forth therefor in Article 7 hereof. Upon termination by either Party for any other reason, the license grants in Section 2.2(a) shall terminate and all rights with respect thereto shall revert in their entirety to Portal; provided that LEO Pharma shall for a period of up to three (3) years have the right to continue to exercise its rights under the license grants in Section 2.2(a) to Exploit the Product, the Product Interface and the Data as is reasonably necessary to complete Products in process and to sell and otherwise Exploit such Products in process and any Products in inventory; provided further that LEO Pharma continues to pay Portal royalties and milestone payments in accordance with this Agreement. Upon termination by either Party for any reason, for a period of twelve (12) months from the effective date of such termination Portal shall continue to perform its obligations under this Agreement and to supply Devices and Cartridges pursuant to the terms of the Manufacturing and Supply Agreement and Section 12.2 shall continue to apply, to enable LEO Pharma to exercise its rights under this Section 17.5(a). In addition, upon termination by LEO Pharma under Section 17.2(b), 17.2(c), 17.2(d), 17.3 or 17.4, (i) LEO Pharma shall have the right to issue one or more purchase orders for Devices and/or Cartridges prior to expiration of such twelve (12) month period, and Portal shall fulfill or cause its Third Party manufacturer to fulfill all such purchase orders (up to a total of twenty percent (20%) over the total number of Devices and/or Cartridges ordered by LEO Pharma during the thirty-six (36) month period prior to the effective date of such termination) and (ii) Portal shall effect a transfer to LEO Pharma or its designee (which designee may be an Affiliate of LEO Pharma or, subject to Portal's consent not to be unreasonably withheld, a Third Party manufacturer) all Information, materials and other technology transfer and assistance to enable the Manufacture, and solely to facilitate implementation of the Manufacture, of Devices and/or Cartridges, as applicable, at facilities designated by LEO Pharma, in accordance with Section 12.2.

(b) For prosecution and maintenance of Joint Patent Rights, Section 10.3(a)(iii) shall survive and apply. If neither Party wishes to pursue or maintain any Patents or Patent Applications associated with Joint Patent Rights, then such Patents or Patent Applications shall be allowed to go abandoned.

(c) For Joint Patent Rights the Parties shall jointly enforce such Patents throughout the Territory and share the costs associated with such enforcement and any recoveries associated therewith as follows: LEO Pharma shall bear or receive fifty percent (50%) of such costs or recovery, as applicable, and Portal shall bear or receive fifty percent (50%) of such costs or recovery, as applicable. If one Party chooses not to participate in enforcement of the Joint Patent Rights, the other Party shall have the right to enforce such Patents (provided all of the costs and expenses of both Parties incurred in connection with such enforcement shall be borne by the enforcing Party), including the right to settle such litigation (subject to the next sentence of this Section 17.5(c)) at its sole expense and to keep all recoveries associated therewith. The joint consent of LEO Pharma and Portal (which consent shall not be unreasonably withheld or delayed) shall be required of any settlement, consent judgment or other voluntary final disposition of a suit under this Section 17.5(c) that could adversely affect the other Party's interest. If, in any enforcement action taken pursuant to this Section 17.5(c), the enforcing Party determines that the other Party is an indispensable party to such action, the other Party hereby consents to be joined

in such action and, in such event, the other Party shall have the right to be represented in such action using counsel of its own choice at the enforcing Party's expense. Notwithstanding the foregoing, each Party's enforcement rights under this Section 17.5(c) shall be subject to limitations imposed in any license agreement with a Third Party existing as of the Effective Date relating to the Patent to be enforced.

17.6 **Surviving Obligations.** The rights and obligations set forth in this Agreement shall extend beyond the expiration or termination of the Agreement only to the extent expressly provided for herein, or to the extent that the survival of such rights or obligations are necessary to permit their complete fulfillment or discharge. Without limiting the foregoing, the following provisions shall survive any expiration or termination of this Agreement: Articles 13, 14, 18 and 19 and Sections 2.2 (subject to Section 17.5), 7.8, 7.10, 9.1, 9.2, 10.3(a)(iii), 12.1, 17.5 and 17.6. Termination of this Agreement shall not terminate LEO Pharma's obligation to pay all Milestone Payments, royalties and other payments which shall have accrued hereunder (including any Milestone Payments then accrued because the event has occurred but the Milestone Payment is not yet due). Except as otherwise provided for in this Agreement, termination by a Party shall not be an exclusive remedy, and all other remedies will be available to the terminating Party, in equity and at law

17.7 **Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by Portal or LEO Pharma are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the United States Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the United States Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the United States Bankruptcy Code, the Party that is not a party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

18. LIMITATION OF LIABILITY AND EXCLUSION OF DAMAGES; DISCLAIMER OF WARRANTY

18.1 **EXCEPT IN THE CASE OF A BREACH OF ARTICLE 14 (CONFIDENTIALITY), AND WITHOUT LIMITING THE PARTIES' OBLIGATIONS UNDER ARTICLE 13 (INDEMNIFICATION) OR ANY LIABILITY FOR FRAUD OR WILLFUL MISCONDUCT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING SUCH DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS OR OTHER ECONOMIC LOSS) ARISING OUT OF THIS AGREEMENT OR WITH RESPECT TO A PARTY'S PERFORMANCE OR NON-PERFORMANCE HEREUNDER**.

18.2 **EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY PROVIDES ANY WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, REGARDING THE PRODUCT, LEO PHARMA'S DRUG OR THE DEVICE AND EACH PARTY HEREBY DISCLAIMS ALL OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND FREEDOM FROM INFRINGEMENT OF THIRD PARTY RIGHTS**.

19. MISCELLANEOUS

19.1 **Agency.** Neither Party is, nor shall be deemed to be, an employee, Agent, co-venturer or legal representative of the other Party for any purpose. Neither Party shall be entitled to enter into any contracts in the name of, or on behalf of, the other Party, nor shall either Party be entitled to pledge the credit of the other Party in any way or hold itself out as having the authority to do so.

19.2 **Assignment.**

(a) Neither this Agreement nor any interest hereunder shall be assignable by any Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld or delayed following the conclusion of the Project); provided, however, (i) the assignment of this Agreement by operation of law pursuant to a Change of Control, merger or consolidation of either Party with or into any Third Party (except, in the case of Portal, Sanofi-Aventis U.S. LLC or any of its Affiliates, including Sanofi Sunrise, or any other pharmaceutical company or biotechnology company that is a direct or indirect competitor of LEO Pharma) shall, regardless of the entity of the surviving entity to such merger or consolidation, not be deemed an assignment in violation of this Section, (ii) either Party without such consent, may transfer or assign its rights and obligations under this Agreement, in whole or from time to time in part, to one or more of its Affiliates (except, in the case of Portal, to Sanofi-Aventis U.S. LLC or any of its Affiliates in the event Sanofi-Aventis U.S. LLC becomes in the future a Portal Affiliate, or any other pharmaceutical company or biotechnology company that is a direct or indirect competitor of LEO Pharma) at any time (provided that such Party agrees to remain primarily (and not secondarily or derivatively) liable for the full and timely performance by such Affiliate of all its obligations hereunder.

(b) This Agreement shall be binding upon and inure to the successors and permitted assignees of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successor's and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 19.2 shall be void.

19.3 **Further Actions.** Each Party shall execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

19.4 **Force Majeure.** Neither Party shall be liable to the other Party for the failure or delay in the performance of any of its obligations under this Agreement or for any losses,

damages or increased costs that the other Party may sustain by reason of such failure or delay of performance, nor shall either Party have any right to terminate this Agreement for any default or delay, for the time and to the extent such failure or delay is attributable to any event beyond its reasonable control and without its fault or negligence, including acts of God, acts of government (including injunctions), fire, flood, earthquake, strike, lockout, labor dispute, civil commotion, acts of public enemies, acts of terrorism or threat of terrorist acts, blockage or embargo and the like (a **"Force Majeure Event"**); provided, however, that in each such case the Party affected shall use commercially reasonable efforts to avoid such occurrence and to resume performance of its obligations as promptly as practicable. The Party affected shall give prompt written notice of any such cause to the other Party. The Party giving such notice shall thereupon be excused from such of its obligations hereunder as it is thereby disabled from performing for so long as it is so disabled and for sixty (60) days thereafter and the Party receiving notice shall be similarly excused from its respective obligations which it is thereby disabled from performing; provided, however, that such affected Party commences and continues to take commercially reasonable actions to cure such cause. Notwithstanding the foregoing, nothing in this Section 19.4 shall excuse or suspend the obligation to make any payment due hereunder in the manner and at the time provided.

19.5 **Notices.** All notices and other communications hereunder shall be delivered in writing and shall be deemed given (a) when delivered, if delivered personally, (b) one (1) Business Day after being sent, if sent by overnight delivery via an international courier service, (c) when transmitted and receipt is confirmed, if by facsimile transmission (receipt verified), or (d) three (3) Business Days after mailing, if mailed by registered or certified mail (return receipt requested), postage prepaid to the Parties at the addresses set forth below in this Section 19.5 (or at such other address for a Party as shall be specified by like notice; provided that notices of a change of address shall be effective only upon receipt thereof). As a courtesy, every notice shall also be sent by the sending Party to the other Party via email to the email addresses set forth below, which email shall not be considered notice under this Agreement.

If to LEO Pharma, addressed to:	LEO Pharma A/S Industriparken 55, 2750 Ballerup Denmark Attention: General Counsel Email: legal@leo-pharma.com With copy (which shall not constitute notice) to: Winston & Strawn LLP 200 Park Avenue New York, New York 10166 USA Attention: Jared Manes E-mail: jmanes@winston.com
If to Portal, addressed to:	CEO 190 5th Street Cambridge, MA 02141

USA

With copy to:

CBO or VP Business Development

19.6 **Amendment.** No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

19.7 **Waiver.** No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its Agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either Party of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

19.8 **Counterparts.** This Agreement may be executed in two counterparts, either one of which need not contain the signature of more than one Party but both such counterparts taken together shall constitute one and the same agreement. The exchange of a fully executed Agreement (in counterparts or otherwise) by electronic transmission in .PDF format shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

19.9 **Construction.** The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement. Except where the context otherwise requires, wherever used the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders. The words "hereof," "herein" and "hereunder" and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The terms "include," "including" and "inclusive of" shall mean "including without limitation." All Exhibits and Schedules annexed hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein. Any capitalized terms used in any Exhibit or Schedule but not otherwise defined therein, shall have the meaning as defined in this Agreement. A reference to any legislation or to any provision of any legislation shall include any modification, amendment, re-enactment thereof, any legislative provision substituted therefore and all rules, regulations and statutory instruments issued or related to such legislation. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. No prior draft of this Agreement nor any course of performance or course of dealing shall be used in the interpretation or construction of this Agreement. No parol evidence shall be introduced in the construction or interpretation of this Agreement unless the ambiguity or uncertainty in issue is plainly discernable from a reading of this Agreement without consideration of any extrinsic evidence.

19.10 **Governing Law.** This Agreement shall be governed by and interpreted in accordance with the substantive laws of the State of New York, U.S.A. without regard to its or any other jurisdiction's choice of law rules. Any disputes under this Agreement shall be brought in

the state or federal courts located in the State of New York, U.S.A.

19.11 **Dispute Resolution.**

(a) Exclusive Dispute Resolution Mechanism. In the event that the Parties cannot reach agreement on a matter arising out of or in connection with this Agreement and any other agreement entered into pursuant hereto or in connection herewith (including matters relating to any Party's rights and/or obligations hereunder and/or regarding the construction, interpretation and enforceability of such agreements), the procedures set forth in this Section 19.11 shall be the exclusive mechanism for resolving any dispute, controversy, or claim in connection with this Agreement, the construction hereof, or the rights, duties or liabilities of either Party under this Agreement (collectively, **"Disputes"**) between the Parties or the JDC that may arise from time to time that cannot be resolved through good faith negotiation between the Parties, except as otherwise set forth herein.

(b) Resolution by Authorized Representatives. Except as otherwise provided in this Agreement, in the event of any Dispute, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within thirty (30) days after one Party provides written notice to the other Party of such Dispute, either Party may, by written notice to the other Party, refer such Dispute to the Authorized Representatives for attempted resolution by good faith negotiation within thirty (30) days after such notice is received. In the event that any Dispute is not resolved under the foregoing provisions, each Party may, at its sole discretion, seek resolution of such Dispute in accordance with Sections 19.11(c) through 19.11(e).

(c) Exclusive Jurisdiction. THE PARTIES IRREVOCABLY ACCEPT THE EXCLUSIVE JURISDICTION OF SUCH COURTS SOLELY AND SPECIFICALLY FOR THE PURPOSE OF ADJUDICATING DISPUTES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT AND ANY OTHER AGREEMENT ENTERED INTO PURSUANT HERETO OR IN CONNECTION HEREWITH (INCLUDING MATTERS REGARDING THE CONSTRUCTION, INTERPRETATION AND ENFORCEABILITY OF SUCH AGREEMENTS), AND IN NO EVENT SHALL ANY PARTY BE DEEMED TO HAVE CONSENTED TO SUCH JURISDICTION FOR ANY OTHER PURPOSE. EACH PARTY FURTHER AGREES THAT SUCH COURTS PROVIDE A CONVENIENT FORUM FOR ANY SUCH ACTION, AND WAIVES ANY OBJECTIONS OR CHALLENGES TO VENUE WITH RESPECT TO SUCH COURTS.

(d) Waiver of Jury Trial. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

(e) Preliminary Injunctions. Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction as provided in Section 19.11(c) to prevent immediate and irreparable injury, loss, or damage on a provisional basis.

19.12 **Severability.** Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under Applicable Law, but if any provision of this Agreement is held to be prohibited by or invalid under Applicable Law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. In the event of such invalidity, the Parties shall seek to agree on an alternative enforceable provision that preserves the original purpose of this Agreement.

19.13 **Entire Agreement of the Parties.** This Agreement and the Exhibits attached hereto, and any other agreements between the Parties effective as of the Effective Date relating to the subject matter hereof, constitute and contain the complete, final and exclusive understanding and agreement of the Parties hereto, and cancel and supersede any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof (including the Confidentiality Agreement to the extent it relates to LEO Pharma's Drug but not to the extent it relates to any other subject matter disclosed thereunder), and neither Party shall be liable or bound to any other Party in any manner by any representations, warranties, covenants, or agreements except as specifically set forth herein or therein. Except as set forth in Article 13, nothing in this Agreement, express or implied, is intended to confer upon any Party, other than the Parties hereto and their respective successors and assigns, any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided herein. To the extent that anything set forth in an Exhibit attached hereto conflicts with the terms of this Agreement, the terms of this Agreement shall control.

19.14 **Performance by Affiliates.**

(a) Portal recognizes that LEO Pharma may perform some or all of its obligations under this Agreement through Affiliates, including the performance of LEO Pharma's obligations arising in or to be performed in the Territory, provided, however, that LEO Pharma shall remain responsible for the performance by its Affiliates and shall use Commercially Reasonable Efforts to cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

(b) LEO Pharma recognizes that Portal may perform some or all of its obligations under this Agreement through Affiliates, provided, however, that Portal shall remain responsible for the performance of its Affiliates and shall use Commercially Reasonable Efforts to cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date by their duly authorized representatives as set forth below:

LEO PHARMA A/S

By:_____
Name: Catherine Mazzacco
Title: President and Chief Executive Officer

By:_____
Name: Anders Kronborg
Title: Executive Vice President

PORTAL INSTRUMENTS, INC.

By:_____
Name: Patrick Anquetil, Ph.D., MBA
Title: CEO

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date by their duly authorized representatives as set forth below:

LEO PHARMA A/S

By:_____
Name: Catherine Mazzacco
Title: President and Chief Executive Officer

By:_____
Name: Anders Kronborg
Title: Executive Vice President

PORTAL INSTRUMENTS, INC.

By:_____
Name: Patrick Anquetil, Ph.D., MBA
Title: CEO

Exhibit 1.40 Development Plan

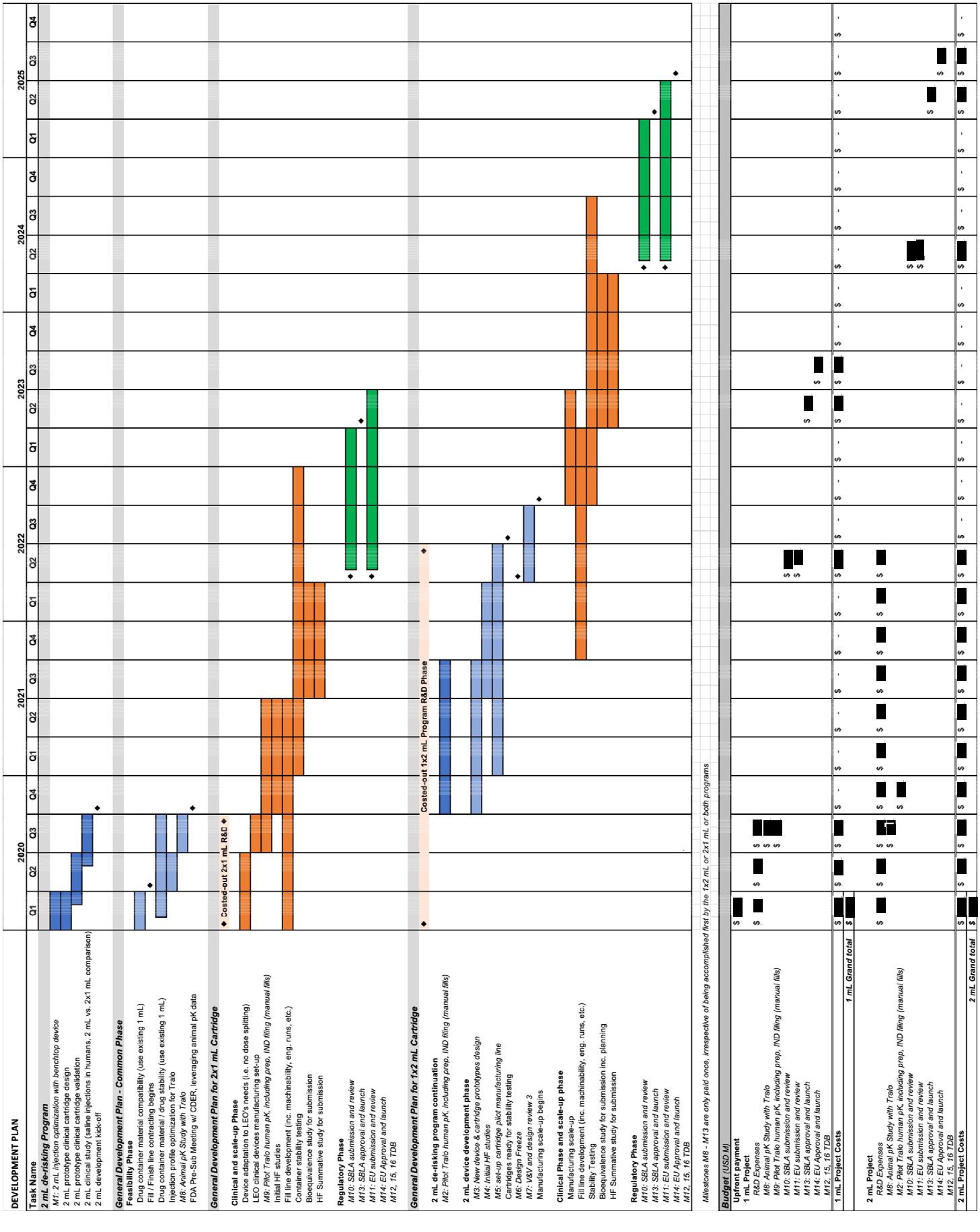

Exhibit 1.105

Portal Patent Rights

TITLE	FILE NUMBER	APPLICATION NUMBER	DATE FILED	PATENT NUMBER	ISSUE DATE	COUNTRY	STATUS	MIT CASE NO.	ASSIGNEE
MEASURING PROPERTIES OF AN ANATOMICAL BODY	PRTL-0002-P02	10657724	Sep 8, 2003	7530975	May 12, 2009	US	Issued	9894	Massachusetts Institute of Technology
MEASURING PROPERTIES OF AN ANATOMICAL BODY	PRTL-0002-PAU	2003272279	Sep 8, 2003	2003272279	Aug 9, 2007	AU	Issued	9894	Massachusetts Institute of Technology
MEASURING PROPERTIES OF AN ANATOMICAL BODY	PRTL-0002-PCA	2497815	Sep 8, 2003	2497815	Jun 11, 2013	CA	Issued	9894	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0003-PCN	2006800063767	Feb 10, 2006	101128230	Sep 29, 2010	CN	Issued	11511(00)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0003-PDE	6020060178077	Feb 10, 2006	1848480	Oct 27, 2010	DE	Issued	11511(00)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0003-PFR	2006720659	Feb 10, 2006	1848480	Oct 27, 2010	FR	Issued	11511 (00)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0003-PGB	2006720659	Feb 10, 2006	1848480	Oct 27, 2010	GB	Issued	11511(00)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0005-P02	11354279	Feb 13, 2006	7833189	Nov 16, 2010	US	Issued	11511(03)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0005-P03	12906525	Oct 18, 2010	8328755	Dec 11, 2012	US	Issued	11511(03)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0005-P04	13708303	Dec 7, 2012	8992466	Mar 31, 2015	US	Issued	11511(03)	Massachusetts Institute of Technology

CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0005-P05	14490126	Sep 18, 2014	9308326	Apr 12, 2016	US	Issued	11511(03)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0005-P06	15066868	Mar 10, 2016	10326347	Jun 18, 2019	US	Issued	11511(03)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0005-PCA	2597666	Feb 13, 2006	2597666	Jul 15, 2014	CA	Issued	11511(03)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0005-PCH	2006720697	Feb 13, 2006	1855739	Sep 16, 2009	CH	Issued	11511(03)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0005-PFR	2006720697	Feb 13, 2006	1855739	Sep 16, 2009	FR	Issued	11511(03)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0005-PGB	067206979	Feb 13, 2006	1855739	Sep 16, 2009	GB	Issued		Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0005-PJP	2007555318	Feb 13, 2006	5113532	Oct 19, 2012	JP	Issued	11511(03)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0005-PNL	2006720697	Feb 13, 2006	1855739	Sep 16, 2009	NL	Issued	11511(03)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0005-PSE	2006720697	Feb 13, 2006	1855739	Sep 16, 2009	SE	Issued	11511(03)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0005-PSG	2007058811	Feb 13, 2006	134672	Jul 30, 2010	SG	Issued	11511(03)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0005-PTW	95104700	Feb 13, 2006	I449549	Aug 21, 2014	TW	Issued	11511(03)	Massachusetts Institute of Technology
NEEDLE-FREE INJECTOR DEVICE WITH AUTOLOADING CAPABILITY	PRTL-0006-P01	12310456	Aug 31, 2007	8172790	May 8, 2012	US	Issued	11511 (02)	Massachusetts Institute of Technology

CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0006-PCA	2666755	Aug 31, 2007	2666755	Mar 25, 2014	CA	Issued	11511 (02)	Massachusetts Institute of Technology
NEEDLE-FREE INJECTOR DEVICE WITH AUTOLOADING CAPABILITY	PRTL-0006-PEP	078116530	Aug 31, 2007			EP	Published	11511 (02)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0006-PHK	910806097	Aug 31, 2007			HK	Published	11511 (02)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0006-PJ1	2013113745	Aug 31, 2007	5824003	Oct 16, 2015	JP	Issued	11511 (02)	Massachusetts Institute of Technology
CONTROLLED NEEDLE-FREE TRANSPORT	PRTL-0006-PJP	2009526752	Aug 31, 2007	5284962	Jun 7, 2013	JP	Issued	11511 (02)	Massachusetts Institute of Technology
INJECTION METHODS USING A SERVO-CONTROLLED NEEDLE-FREE INJECTOR	PRTL-0007-P01	13269421	Oct 7, 2011	8740838	Jun 3, 2014	US	Issued	11512	Massachusetts Institute of Technology
Injection Methods Using A Servo-Controlled Needle-Free Injector	PRTL-0007-P03	15338038	Oct 28, 2016			US	Published	11512	Massachusetts Institute of Technology
INJECTION METHODS USING A SERVO-CONTROLLED NEEDLE-FREE INJECTOR	PRTL-0007-PCH	117879544	Oct 7, 2011	2621564	Oct 5, 2016	CH	Issued	11512	Massachusetts Institute of Technology
INJECTION METHODS USING A SERVO-CONTROLLED NEEDLE-FREE INJECTOR	PRTL-0007-PCN	201180058910X	Oct 7, 2011	CN103269737	Jun 6, 2017	CN	Issued	11512	Massachusetts Institute of Technology

INJECTION METHODS USING A SERVO-CONTROLLED NEEDLE-FREE INJECTOR	PRTL-0007-PDE	6020110310275	Oct 7, 2011	602011031027.5	Oct 5, 2016	DE	Issued	11512	Massachusetts Institute of Technology
INJECTION METHODS USING A SERVO-CONTROLLED NEEDLE-FREE INJECTOR	PRTL-0007-PEP	117879544	Oct 7, 2011	2621564	Oct 5, 2016	EP	Issued	11512	Massachusetts Institute of Technology
INJECTION METHODS USING A SERVO-CONTROLLED NEEDLE-FREE INJECTOR	PRTL-0007-PFR	117879544	Oct 7, 2011	2621564	Oct 5, 2016	FR	Issued	11512	Massachusetts Institute of Technology
INJECTION METHODS USING A SERVO-CONTROLLED NEEDLE-FREE INJECTOR	PRTL-0007-PGB	117879544	Oct 7, 2011	2621564	Oct 5, 2016	GB	Issued	11512	Massachusetts Institute of Technology
INJECTION METHODS USING A SERVO-CONTROLLED NEEDLE-FREE INJECTOR	PRTL-0007-PHK	141011474	Oct 7, 2011			HK	Published	11512	Massachusetts Institute of Technology
INJECTION METHODS USING A SERVO-CONTROLLED NEEDLE-FREE INJECTOR	PRTL-0007-PJ1	2016-157736	Oct 7, 2011	JP6338624B2	Jun 6, 2018	JP	Issued	11512	Massachusetts Institute of Technology
INJECTION METHODS USING A SERVO-CONTROLLED NEEDLE-FREE INJECTOR	PRTL-0007-PNL	117879544	Oct 7, 2011	2621564	Oct 5, 2016	NL	Issued	11512	Massachusetts Institute of Technology
INJECTION METHODS USING A SERVO-CONTROLLED NEEDLE-FREE INJECTOR	PRTL-0007-PSE	117879544	Oct 7, 2011	2621564	Oct 5, 2016	SE	Issued	11512	Massachusetts Institute of Technology

BIDIRECTIONAL MOTION OF A LORENTZ-FORCE ACTUATED NEEDLE-FREE INJECTOR (Nfi)	PRTL-0009-P03	12879787	Sep 10, 2010	8398583	Mar 19, 2013	US	Issued	13318	Massachusetts Institute of Technology
BIDIRECTIONAL MOTION OF A LORENTZ-FORCE ACTUATED NEEDLE-FREE INJECTOR (Nfi)	PRTL-0009-P04	12960405	Dec 3, 2010	9125990	Sep 8, 2015	US	Issued	13318	Massachusetts Institute of Technology
BI-DIRECTIONAL MOTION OF A LORENTZ-FORCE ACTUATED NEEDLE-FREE INJECTOR (Nfi)	PRTL-0009-P05	14504903	Oct 2, 2014	9789256	Oct 17, 2017	US	Issued	13318	Massachusetts Institute of Technology
BI-DIRECTIONAL MOTION OF A LORENTZ-FORCE ACTUATED NEEDLE-FREE INJECTOR (Nfi)	PRTL-0009-P06	15728988	Oct 10, 2017			US	Allowed	13318	Massachusetts Institute of Technology
Nonlinear System Identification Techniques and Devices for Discovering Dynamic and Static Tissue Properties	PRTL-0010-P01	12872630	Aug 31, 2010	8758271	Jun 24, 2014	US	Issued	13836	Massachusetts Institute of Technology
NONLINEAR SYSTEM IDENTIFICATION TECHNIQUES AND DEVICES FOR DISCOVERING DYNAMIC AND STATIC TISSUE PROPERTIES	PRTL-0010-P02	14310744	Jun 20, 2014	9517030	Dec 13, 2016	US	Issued	13836	Massachusetts Institute of Technology

Nonlinear System Identification Techniques And Devices For Discovering Dynamic And Static Tissue Properties	PRTL-0010-P03	15342718	Nov 3, 2016			US	Allowed	13836	Massachusetts Institute of Technology
DELIVERY OF A SOLID BODY AND/OR A FLUID USING A LINEAR LORENTZ-FORCE ACTUATED NEEDLE-FREE JET INJECTION SYSTEM	PRTL-0013-P01	13269322	Oct 7, 2011	8821434	Sep 2, 2014	US	Issued	14530	Massachusetts Institute of Technology
DELIVERY OF A SOLID BODY AND/OR A FLUID USING A LINEAR LORENTZ-FORCE ACTUATED NEEDLE-FREE JET INJECTION SYSTEM	PRTL-0013-PCN	2011800589114	Oct 7, 2011	103298507	Aug 26, 2015	CN	Issued	14530	Massachusetts Institute of Technology
DELIVERY OF A SOLID BODY AND/OR A FLUID USING A LINEAR LORENTZ-FORCE ACTUATED NEEDLE-FREE JET INJECTION SYSTEM	PRTL-0013-PDE	117882431	Oct 7, 2011	602011050008.2.	Jul 11, 2018	DE	Issued		Massachusetts Institute of Technology
DELIVERY OF A SOLID BODY AND/OR A FLUID USING A LINEAR LORENTZ-FORCE ACTUATED NEEDLE-FREE JET INJECTION SYSTEM	PRTL-0013-PE1	181773102	Oct 7, 2011			EP	Published	14530	Massachusetts Institute of Technology

DELIVERY OF A SOLID BODY AND/OR A FLUID USING A LINEAR LORENTZ-FORCE ACTUATED NEEDLE-FREE JET INJECTION SYSTEM	PRTL-0013-PEP	117882431	Oct 7, 2011	EP2621565	Jul 11, 2018	EP	Issued	14530	Massachusetts Institute of Technology
DELIVERY OF A SOLID BODY AND/OR A FLUID USING A LINEAR LORENTZ-FORCE ACTUATED NEEDLE-FREE JET INJECTION SYSTEM	PRTL-0013-PFR	117882431	Oct 7, 2011	EP2621565	Jul 11, 2018	FR	Issued		Massachusetts Institute of Technology
DELIVERY OF A SOLID BODY AND/OR A FLUID USING A LINEAR LORENTZ-FORCE ACTUATED NEEDLE-FREE JET INJECTION SYSTEM	PRTL-0013-PGB	117882431	Oct 7, 2011	EP2621565	Jul 11, 2018	GB	Issued		Massachusetts Institute of Technology
DELIVERY OF A SOLID BODY AND/OR A FLUID USING A LINEAR LORENTZ-FORCE ACTUATED NEEDLE-FREE JET INJECTION SYSTEM	PRTL-0013-PHK	141011483	Oct 7, 2011			HK	Published	14530	Massachusetts Institute of Technology
DELIVERY OF A SOLID BODY AND/OR A FLUID USING A LINEAR LORENTZ-FORCE ACTUATED NEEDLE-FREE JET INJECTION SYSTEM	PRTL-0013-PJP	2013532987	Oct 7, 2011	JP5934710	Jun 15, 2016	JP	Issued	14530	Massachusetts Institute of Technology

AUTOMATED METHOD FOR SIMULTANEOUS BUBBLE DETECTION AND EXPULSION	PRTL-0014-P01	14528771	Oct 30, 2014	9486589	Nov 8, 2016	US	Issued	16680	Massachusetts Institute of Technology
FLUID TRANSFER MECHANISM FOR NEEDLE-FREE INJECTION DEVICE	PRTL-0015-P01	14879517	Oct 9, 2015			US	Published		Portal Instruments, Inc.
FLUID TRANSFER MECHANISM FOR AN INJECTION DEVICE	PRTL-0016-P01	15288429	Oct 7, 2016			US	Published		Portal Instruments, Inc.
NEEDLE-FREE INJECTION GUIDE	PRTL-0017-P01	15357036	Nov 21, 2016			US	Published		Portal Instruments, Inc.
APPARATUS FOR REINFORCING SYRINGE CARTRIDGE	PRTL-0018-P01	15420185	Jan 31, 2017			US	Published		Portal Instruments, Inc.
SLEEVE FOR REINFORCING SYRINGE CARTRIDGE	PRTL-0018-P02	15420222	Jan 31, 2017			US	Published		Portal Instruments, Inc.
BIOSPECIMEN EXTRACTION APPARATUS	PRTL-0019-P01	15378205	Dec 14, 2016			US	Published		Portal Instruments, Inc.
NEEDLE-FREE TRANSDERMAL INJECTION DEVICE	PRTL-0020-P01	14952056	Nov 25, 2015			US	Published		Portal Instruments, Inc.
NEEDLE-FREE TRANSDERMAL INJECTION DEVICE	PRTL-0020-PCN	2016800692457	Nov 22, 2016			CN	Published		Portal Instruments, Inc.
NEEDLE-FREE TRANSDERMAL INJECTION DEVICE	PRTL-0020-PEP	168092666	Nov 22, 2016			EP	Published		Portal Instruments, Inc.

ANGLED INJECTION NOZZLE	PRTL-0021-P01	15454426	Mar 9, 2017			US	Published		Portal Instruments, Inc.
NOZZLE FOR USE IN AN ULTRA-HIGH VELOCITY INJECTION DEVICE	PRTL-0025-P01	14788001	Jun 30, 2015	10159793	Dec 25, 2018	US	Issued		Portal Instruments, Inc.
NOZZLE FOR USE IN AN ULTRA-HIGH VELOCITY INJECTION DEVICE	PRTL-0025-P02	15819296	Nov 21, 2017	10207055	Feb 19, 2019	US	Issued		Portal Instruments, Inc.
SIDE-ANGLE DECAPPING OF PRE-FILLED SYRINGE	PRTL-0026-P01	15598653	May 18, 2017	10376656	Aug 13, 2019	US	Issued		Portal Instruments, Inc.
CONNECTED HEALTH PLATFORM INCLUDING NEEDLE-FREE INJECTOR SYSTEM	PRTL-0027-P01	15368145	Dec 2, 2016			US	Published		Portal Instruments, Inc.
DEVICE FOR TREATMENT COMPLIANCE AND EVENT TRACKING	PRTL-0028-P01	15796164	Oct 27, 2017			US	Published		Portal Instruments, Inc.
ROTARY MOTOR BASED TRANSDERMAL INJECTION DEVICE	PRTL-0029-P01	16129241	Sep 12, 2018	10413671	Sep 17, 2019	US	Issued		Portal Instruments, Inc.
ROTARY MOTOR BASED TRANSDERMAL INJECTION DEVICE	PRTL-0029-PWO	PCTUS1850643	Sep 12, 2018			WO	Published		Portal Instruments, Inc.
ENCODING INFORMATION FOR DRUG DELIVERY	PRTL-0030-P01	15801701	Nov 2, 2017			US	Published		Portal Instruments, Inc.

METHOD AND DEVICE FOR DELIVERING A SUBCUTANEOUS DOSE THROUGH MULTIPLE INJECTIONS	PRTL-0031-P01	15824056	Nov 28, 2017			US	Published		Portal Instruments, Inc.
ACTIVE INJECTION GUIDE	PRTL-0032-P01	16400290	1-May-19			US	Pending		Portal Instruments, Inc.
ACTIVE INJECTION GUIDE	PRTL-0032-PWO	PCT/US19/30096	1-May-19			PCT	Pending		Portal Instruments, Inc.

Exhibit 1.107 Portal Trademarks

Owner	Trademark	Image	Country	Application No	Registration No	Registration Date	Int. Classes	Trademark Status
Portal Instruments, Inc.	ABSTERA	ABSTERA	Australia	1919370	1396675	Nov 29 2017	10, 44	Registered
Portal Instruments, Inc.	ABSTERA	ABSTERA	China	1396675	1396675	Nov 29 2017	10, 44	Registered
Portal Instruments, Inc.	ABSTERA	ABSTERA	EUTM	1396675	1396675	Nov 29 2017	10, 44	Registered
Portal Instruments, Inc.	ABSTERA	ABSTERA	Japan	1396675	1396675	Nov 29 2017	10, 44	Registered
Portal Instruments, Inc.	ABSTERA	ABSTERA	Mexico	1396675	1396675	Nov 29 2017	10	Registered
Portal Instruments, Inc.	ABSTERA	ABSTERA	Mexico	1396675	1396675	Nov 29 2017	44	Registered
Portal Instruments, Inc.	ABSTERA	ABSTERA	New Zealand	1396675	1396675	Nov 29 2017	10, 44	Registered
Portal Instruments, Inc.	ABSTERA	ABSTERA	Republic of Korea (South)	1396675	1396675	Nov 29 2017	10, 44	Registered
Portal Instruments, Inc.	ABSTERA	ABSTERA	United States of America	87493606			10, 44	Pending
Portal Instruments, Inc.	ABSTERA	ABSTERA	WIPO	1396675	1396675	Nov 29 2017	10, 44	Registered
Portal Instruments, Inc.	NURSE IN YOUR POCKET	NURSE IN YOUR POCKET	United States of America	87219444			42	Pending
Portal Instruments, Inc.	O DESIGN		Australia	1845523	1344822	Feb 6 2017	10	Registered
Portal Instruments, Inc.	O DESIGN		China	1344822	1344822	Feb 6 2017	10	Registered
Portal Instruments, Inc.	O DESIGN		EUTM	1344822	1344822	Feb 6 2017	10	Registered
Portal Instruments, Inc.	O DESIGN		Japan	1344822	1344822	Feb 6 2017	10	Registered
Portal Instruments, Inc.	O DESIGN		Mexico	1860234	1344822	Feb 6 2017	10	Registered
Portal Instruments, Inc.	O DESIGN		New Zealand	1066968	1344822	Feb 6 2017	10	Registered
Portal Instruments, Inc.	O DESIGN		Republic of Korea (South)	1344822	1344822	Feb 6 2017	10	Registered
Portal Instruments, Inc.	O DESIGN		United States of America	87147400			10	Pending
Portal Instruments, Inc.	O DESIGN		WIPO	1344822	1344822	Feb 6 2017	10	Registered
Portal Instruments, Inc.	PORTAL	PORTAL	Australia	1740403	1277739	Oct 29 2015	10	Registered
Portal Instruments, Inc.	PORTAL	PORTAL	China	1277739	1277739	Oct 29 2015	10	Refused
Portal Instruments, Inc.	PORTAL	PORTAL	Japan	1277739	1277739	Oct 29 2015	10	Refused
Portal Instruments, Inc.	PORTAL	PORTAL	Mexico	1277739	1277739	Oct 29 2015	10	Registered
Portal Instruments, Inc.	PORTAL	PORTAL	New Zealand	1033592	1277739	Oct 29 2015	10	Registered
Portal Instruments, Inc.	PORTAL	PORTAL	Republic of Korea (South)	1277739	1277739	Oct 29 2015	10	Refused
Portal Instruments, Inc.	PORTAL	PORTAL	United States of America	86617375	5643769	Jan 1 2019	10	Registered
Portal Instruments, Inc.	PORTAL	PORTAL	WIPO	1277739	1277739	Oct 29 2015	10	Registered
Portal Instruments, Inc.	PORTAL INSTRUMENTS	PORTAL INSTRUMENTS	Australia	1740394	1277709	Oct 29 2015	10	Registered
Portal Instruments, Inc.	PORTAL INSTRUMENTS	PORTAL INSTRUMENTS	China	1277709	1277709	Oct 29 2015	10	Refused
Portal Instruments, Inc.	PORTAL INSTRUMENTS	PORTAL INSTRUMENTS	EUTM	1277709	1277709	Oct 29 2015	10	Registered
Portal Instruments, Inc.	PORTAL INSTRUMENTS	PORTAL INSTRUMENTS	Japan	1277709	1277709	Oct 29 2015	10	Registered
Portal Instruments, Inc.	PORTAL INSTRUMENTS		Mexico	1277709	1277709	Oct 29 2015	10	Registered
Portal Instruments, Inc.	PORTAL INSTRUMENTS		New Zealand	1277709	1277709	Oct 29 2015	10	Registered
Portal Instruments, Inc.	PORTAL INSTRUMENTS		Republic of Korea (South)	1277709	1277709	Oct 29 2015	10	Refused
Portal Instruments, Inc.	PORTAL INSTRUMENTS		United States of America	86616844	5829178	Aug 6 2019	10	Registered
Portal Instruments, Inc.	PORTAL INSTRUMENTS		WIPO	1277709	1277709	Oct 29 2015	10	Registered
Portal Instruments, Inc.	PORTAL INSTRUMENTS & DESIGN		Australia	1344256	1344256	Feb 6 2017	10	Registered
Portal Instruments, Inc.	PORTAL INSTRUMENTS & DESIGN		China	1344256	1344256	Feb 6 2017	10	Refused
Portal Instruments, Inc.	PORTAL INSTRUMENTS & DESIGN		EUTM	1277739	1277739	Oct 29 2015	10	Registered
Portal Instruments, Inc.	PORTAL INSTRUMENTS & DESIGN		EUTM	1344256	1344256	Feb 6 2017	10	Registered
Portal Instruments, Inc.	PORTAL INSTRUMENTS & DESIGN		Japan	1344256	1344256	Feb 6 2017	10	Registered
Portal Instruments, Inc.	PORTAL INSTRUMENTS & DESIGN		Mexico	1344256	1344256	Feb 6 2017	10	Registered
Portal Instruments, Inc.	PORTAL INSTRUMENTS & DESIGN		New Zealand	1344256	1344256	Feb 6 2017	10	Registered
Portal Instruments, Inc.	PORTAL INSTRUMENTS & DESIGN		Republic of Korea (South)	1344256	1344256	Feb 6 2017	10	Refused
Portal Instruments, Inc.	PORTAL INSTRUMENTS & DESIGN		United States of America	87147352			10	Pending
Portal Instruments, Inc.	PORTAL INSTRUMENTS & DESIGN		WIPO	1344256	1344256	Feb 6 2017	10	Registered
Portal Instruments, Inc.	PORTAL THERAPEUTICS		United States of America	88564064			10, 44	Pending
Portal Instruments, Inc.	PRIME		United States of America	88564021			10	Pending

Exhibit 7.4

Sample Calculations of Royalty Payments

Net Sales in the Territory during the first Calendar Quarter of a particular Calendar Year (all of which occurred at a time when there ***was a Valid Claim*** of Portal Patent Rights covering sold Product in each country in the Territory at the time of Net Sales of such Product in such country) is $225,000,000.

Royalty payable for first Calendar Quarter = $225,000,000 * [redacted] = $[redacted]

Net Sales in the Territory during the second Calendar Quarter of the same Calendar Year (all of which occurred at a time when there ***was a Valid Claim*** of Portal Patent Rights covering sold Product in each country in the Territory at the time of Net Sales of such Product in such country) is $400,000,000.

Royalty payable for second Calendar Quarter = (($500,000,000-$225,000,000) * [redacted]) + ((($400,000,000-($500,000,000-$225,000,000)) * [redacted]) = $[redacted] + [redacted] = $[redacted]

Net Sales in the Territory during the third Calendar Quarter of the same Calendar Year (all of which occurred at a time when there ***was a Valid Claim*** of Portal Patent Rights covering sold Product in each country in the Territory at the time of Net Sales of such Product in such country) is $600,000,000.

Royalty payable for third Calendar Quarter = (($1,000,000,000 – ($225,000,000 + $400,000,000) * [redacted]) + ($600,000,000 - (($1,000,000,000 – ($225,000,000 + $400,000,000))) * [redacted]) = $[redacted] + $[redacted] = $[redacted]

Net Sales in the Territory during the fourth Calendar Quarter of the same Calendar Year (all of which occurred at a time when there was ***no Valid Claim*** of Portal Patent Rights covering sold Product in any country in the Territory at the time of Net Sales of such Product in such country) is $200,000,000.

Royalty payable for fourth Calendar Quarter = ($1,425,000,000 - $1,000,000,000 - $225,000,000) * ([redacted] * 0.5) = $[redacted]

Exhibit 8.2

Key Terms for Manufacturing and Supply Agreement

The following proposal outlines the key terms of the Manufacturing and Supply Agreement to be negotiated in accordance with this Agreement. It does not describe all of the terms and conditions to be included in the Manufacturing and Supply Agreement.

<table>
<tr><td colspan="2">SCOPE OF SUPPLY AGREEMENT</td></tr>
<tr><td>Products</td><td>Needle-free drug delivery system</td></tr>
<tr><td>Manufacturing Lead Time</td><td>To be determined. Lead time will depend on the forecasts and development pathway (1 mL vs. 2 mL cartridge) as chosen by LEO Pharma.</td></tr>
<tr><td>Forecast Requirements</td><td>• Firm forecasts will be required for Portal to establish and meet pricing listed in this Exhibit 8.2
• For annual forecasts of under 300,000 cartridges and under 10,000 devices Portal shall be ready to supply upon device and cartridge device verification (can utilize existing infrastructure)</td></tr>
<tr><td>Capacity</td><td>Annual forecasts of over 300,000 Cartridges and over 10,000 Devices require advance notice:
• Up to 2 years for Cartridges (due to needed transition from a semi-automated line to automated line); and
• Up to 1 year for Devices (due to manufacturing transfer from low volume manufacturer to high volume manufacturer).</td></tr>
<tr><td>Price of Devices (Commercial and Clinical)</td><td>LEO Pharma shall pay Portal, on an ongoing basis, for the supply of the Devices for use in Development (including Clinical Trials of the Product) and in the Manufacture of commercial supplies of the Product at a price equal to one hundred and fifteen (115%) of Portal’s Fully Burdened Manufacturing Cost thereof, subject to the maximum price per Device set forth in the following table:
<table>
<tr><th>Aggregate Volume Manufactured During the Term of the Supply Agreement</th><th>Maximum Price Per Device</th></tr>
<tr><td>0-10,000 (semi-automated production)</td><td>USD 600</td></tr>
<tr><td>10,001-100,000</td><td>To be calculated by interpolating between the < 10,000 volume maximum price per Device (USD 600) and the 100,001+ volume maximum price per Device (USD 250)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td>
<table>
<tr><td>100,001+ (fully automated production)</td><td>USD 250</td></tr>
</table>
</td></tr>
<tr><td>Price of Cartridges (Commercial and Clinical)</td><td>LEO Pharma shall pay Portal, on an ongoing basis, for the supply of the Cartridges for use in Development (including Clinical Trials of the Product) and in the Manufacture of commercial supplies of the Product at a price equal to one hundred and fifteen (115%) of Portal's Fully Burdened Manufacturing Cost thereof, subject to the maximum price per Cartridge set forth in the following table:

<table>
<tr><th>Aggregate Volume Manufactured During the Term of the Supply Agreement</th><th>Maximum Price Per Cartridge</th></tr>
<tr><td>0-300,000</td><td>USD 3</td></tr>
<tr><td>300,001-3,000,000</td><td>To be calculated by interpolating between the < 300,000 volume maximum price per Cartridge (USD 3) and the 3,000,001+ volume maximum price per Cartridge (USD 1)</td></tr>
<tr><td>3,000,001+</td><td>USD 1</td></tr>
</table>

The maximum price per Cartridge shall be as listed in the table above, regardless of the volume capacity of the Cartridge (e.g., 1mL or 2mL).</td></tr>
<tr><td>Fully Burdened Manufacturing Cost</td><td>"Fully Burdened Manufacturing Costs" means, as applicable to a Device or Cartridge manufactured by Portal or its Third Party supplier, Portal's or its Affiliate's cost of manufacturing such Device or Cartridge for Development or Commercial purposes, which is equal to the sum of (a) for a Device or Cartridge (or components thereof) made by Portal, the costs of all direct material (the actual costs incurred in manufacturing or purchasing materials for manufacture), direct labor (the actual cost of employees engaged in direct manufacturing activities and quality control and quality assurance activities who are directly employed by Portal in manufacturing the Device or Cartridge (or components thereof)), and allocable manufacturing overhead (which shall not include any corporate or non-manufacturing site specific administrative overhead costs, plant start-up costs or costs associated with excess or idle capacity) consumed, provided or procured by Portal, in each case for the Manufacture of the Device, and (b) for a Device or Cartridge (or components thereof) made by Portal's Third Party supplier, the actual out-of-pocket costs paid to such Third Party supplier by Portal for the manufacture of such Device or Cartridge (or components thereof), to the extent such costs in (a) and (b) are incurred by Portal or its Affiliates and to the extent they are reasonably allocable to the manufacture of such Device or Cartridge. Fully Burdened Manufacturing Cost shall be calculated in a manner consistent with GAAP.</td></tr>
<tr><td>Inspection</td><td>LEO Pharma or an appointed third party shall have 90 days from receiving a shipment of Products to inspect and exercise reasonable judgement to either</td></tr>
</table>

	accept or notify Portal of non-conforming Products. The acceptance of any shipments by LEO Pharma shall not restrict LEO Pharma from making any claims related to hidden defects, which had not been discovered and would not have reasonably been discoverable by LEO Pharma as part of the inspection.
Quality	Portal shall manufacture Devices and Cartridges that conform to LEO Pharma's specifications.
Manufacturing Lines	Portal will either stand up new manufacturing lines or utilize existing manufacturing lines depending on the development path chosen by LEO Pharma.
Term and Termination	Will contain customary termination rights but, in addition, the Term shall end upon the earlier of (i) expiration or termination of the Agreement, or (ii) the end of LEO Pharma's obligation to pay royalties to Portal based on Net Sales of Product.
Quality Defects, Recalls and Complaints	Portal will investigate all Device and Cartridge quality defects, deviations or complaints related to Portal's manufacturing activities, including root cause analysis, impact, actions taken for correction of the problem, prevention of future occurrence and a formal conclusion. Portal shall perform trending of such quality-related events and provide summary reports to LEO Pharma. In case investigations are required in connection with recalls related to the Device or Cartridge, Portal will promptly perform all due activities and provide all relevant documentation and findings to LEO Pharma. Recalls related solely to the Device and/or Cartridge will be at the cost of Portal.
Audit	Regulatory authorities, including FDA and EMA, will have a right to audit. Furthermore, upon prior written notice, LEO Pharma, or its designated third parties, will have the right to audit Portal and Portal's third-party manufacturers of the Device and Cartridge.

Exhibit 12.4

Term Sheet for Data Sharing Agreement and FAQs

The following proposal sets out the key principles and terms for a data sharing agreement between LEO Pharma and Portal that will govern the use of data in the development, testing and subsequent use of the Product Interface (as defined in the Collaboration and License Agreement between LEO Pharma and Portal (the **"Collaboration Agreement"**). The terms described below will be used to inform a full data sharing agreement, both for clinical and commercial scale, to be negotiated in the future. The terms also provide information in the Annex on the features of the product that will enable LEO Pharma and Portal to comply with Europe's General Data Protection Regulation (**"GDPR"**) and other potentially applicable laws (e.g., the United States' Health Insurance Portability and Accountability Act (**"HIPAA"**) and the California Consumer Privacy Act (**"CCPA"**). It does not describe all of the conditions required for a full data sharing agreement.

SCOPE OF DATA SHARING AGREEMENT	
Parties and Role	For the development phase of the Product Interface, LEO Pharma and Portal is expected to be joint controllers of any personal data used to develop/train the Product. For the commercial phase of the Product Interface, LEO Pharma and Portal will be each be independent controllers of personal data. To the extent that Portal shall process data on behalf of LEO Pharma, the Parties will enter into a Data Processing Agreement and, if relevant, a Data Transfer Agreement or other similar agreement required by applicable law.
Governance	The Joint Development Committee ("JDC") will coordinate activities and communications with respect to development of the Product Interface, to consult on the Product Interface features and functionality to ensure the Product Interface complies with applicable privacy law and discuss the physical, technical and organisational measures to be implemented to ensure the security and privacy of any personal data for the Product Interface. JDC will be responsible, *inter alia*, for: (i) consulting on the development of the Product Interface (including back-end systems and other connectivity features of the Device) generally and ensuring that it is developed in accordance with in compliance with the principles of privacy by design and applicable data protection laws, including the principles set out in the FAQs; (ii) allocating responsibilities for communicating with the relevant data subjects regarding the processing of personal data (including, if applicable, obtaining any necessary consents for the development phase of the Product Interface.); (iii) serving as a forum for exchanging information regarding the parties' processing of personal data in order to ensure that such processing is compliant with applicable data protection laws and consistent with relevant

	consents and privacy policies (including, as applicable, with respect to independent activities; (iv) discussing any relevant changes to data privacy and protection laws that may require changes to processing activities; and (iv) agreeing to any necessary changes to the data sharing agreement. The JDC will meet as set forth in the Collaboration Agreement. The data sharing agreement may further define the day-to-day roles and responsibilities attributed to the JDC members in connection with the above tasks.
Development Phase	The data sharing agreement will document each party's respective responsibilities for compliance with the GDPR for the development phase of the Product Interface. Each party will ensure that the essence of that arrangement is communicated to any data subjects whose data is processed during the development phase. The parties understand that their respective roles (e.g., as joint or independent controllers) may change as plans regarding the Device, the Product Interface and the clinical trials evolve. That stated, where Portal and LEO Pharma are joint controllers of personal data, they will each and will cause their officers, employees, agents, attorneys, consultants, advisors and other representatives to address relevant legal requirements and data privacy and security best practices by: • processing such personal data in accordance with applicable data privacy and protection laws and solely for the purposes disclosed to the relevant data subjects and purposes compatible with such purposes (including, if applicable, any privacy policies and consents provided in relation to the processing of such data) and subject to the allocation of responsibilities set out in the data sharing agreement; • implementing appropriate technical and organizational measures to ensure a level of security appropriate to the risk, taking into account the state of the art, relevant legal requirements and industry standards, the costs of implementation and the nature, scope, context and purpose of processing and promptly notify the other party if any personal data is subject to any unauthorized or unlawful use, access, acquisition, disclosure, loss, destruction or damage. Save as agreed by the JDC, Portal shall be responsible for the technical and organisation measures for the Product Interface and connected cloud storage; and • neither party shall further disclose the personal data to any third party (including, for clarity, any subcontractors) absent appropriate written agreements (in accordance with relevant legal requirements) or otherwise in a manner incompatible with the fair processing information provided to the relevant data subjects;

	• to the extent a party provides or procures the provision of personal data to assist in the development and testing of the Product Interface such party shall be responsible for ensuring there is a valid legal basis and that all necessary information has been communicated to that data subject in accordance with Articles 12 to 14 of the GDPR (or other relevant legal requirements); • to the extent that either party wishes to de-identify or aggregate personal data, ensure that such data is de-identified or aggregated in accordance with relevant legal requirements; • unless otherwise agreed in writing, each party, will pass on the details of any request from a data subject for the rectification or erasure of their personal data, or other right enumerated to the individual under applicable laws, to the party that provides or procures the provision of the data of the data subject in question and provide any reasonable assistance as is reasonably required for the purposes of responding to the data subject request in accordance with any data protection law; • Portal shall be responsible for complying with any data export rules for any onward transfer of the data required for operation of the Product Interface in the development stage and ensuring all requirements for the appointment of sub-processors are met. To the extent that Portal transfers personal data outside the EEA, it will implement and maintain appropriate transfer mechanisms and security safeguards to address relevant legal requirements, such as executing approved standard contractual clauses and implementing data processing addendums with sub-processors; • Portal may use sub-processors in the development phase and will be responsible for ensuring compliance with Article 28 of the GDPR to ensure that any sub-processor provides sufficient safeguards to ensure compliance with GDPR. LEO Pharma will have approval rights over the use of any such sub-processors and will work with Portal to ensure that all sub-processors are sufficiently vetted prior to receiving personal data. Portal will develop in consultation with LEO Pharma a record of processing for the Product Interface. • Portal shall be responsible for the reporting of any security incidents affecting information technology infrastructure that houses personal data and personal data breaches which occur during the development phase. LEO Pharma shall provide such assistance as is reasonably required by Portal to investigate such incidents. In the event of an incident caused by LEO Pharma, Portal shall also provide all assistance as is reasonably required by LEO Pharma to investigate such incidents and meet all necessary legal requirements (e.g., notification to third parties).
Commercial Phase	From commercial launch, where Portal and LEO Pharma process personal data as independent controllers for their own respective purposes, they will comply with the following obligations:

	• Subject to compliance with the GDPR and any other applicable data privacy and protection laws (which may require seeking user consent and offering opt-outs), Portal shall be able to use the data for its own purposes including using it to for statistical analysis and research, including producing reports on an aggregated and de-identified basis, so long as such information is aggregated and de-identified according to relevant legal standards. • Use cases by LEO Pharma will be agreed by the parties so that Portal can disclose any processing by LEO Pharma in the privacy policy presented on the App (if required by law), and consent sought, where necessary through the Product Interface. LEO Pharma will provide any information which Portal reasonably requires in order to provide data subjects with the requisite information regarding LEO Pharma's processing activities. • LEO Pharma shall have the right to approve any privacy policies and/or consent language used by Portal in connection with the Device, the Product Interface, or the clinical trials • Portal will ensure that the Product Interface includes functionality to ensure that data subjects are provided with all required information in relation to each party's data processing activities and allows data subjects to consent on a purpose-by-purpose basis to such data processing, including for the sharing of such personal data with third parties. • Portal shall track all consents (and corresponding consent language) and opt-outs. • Each party will ensure that persons authorised to process the personal data have received appropriate training and committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality. • Each party will implement appropriate physical, technical and organisational measures to ensure compliance with relevant legal requirements and a level of security appropriate to the risk to individuals. • Each party will notify the other without undue delay after becoming aware of security incidents affecting information technology assets housing personal data or personal data breaches and shall consult with the other party and provide any necessary information reasonably required by the other party to assist in investigating and reporting such breach. Costs associated with the breach, including investigation, notification and regulatory investigations • To the extent that either party transfers personal data outside the EEA, it will implement and maintain appropriate transfer mechanisms and security safeguards to address relevant legal requirements, such as executing approved standard contractual clauses and implementing data processing addendums with sub-processors.
Term and Termination	Described in the Collaboration Agreement.

Indemnities	Agreement to contain customary indemnities.
Limits on Liability	Limitations on liability will mirror Clause 18 of the above agreement, excluding liability for special, indirect, incidental, punitive or consequential damages (including such damages resulting from loss of use, loss of profits, interruption or loss of business or other economic loss) arising out of the data sharing agreement or with respect to a party's performance or non-performance. Exclusions on such damages shall not apply to liability associated with violations of privacy and security laws, or losses associated with security breaches and violations of any Data Processing Addendums (or similar agreements).

FAQs re GDPR

What types of Personal Data will be processed by the Product Interface?

The JDC will agree on the final data fields, but the Product Interface will process personal data necessary to optimize the use of the Device in managing the patient's condition, including name, date of birth, address, email address, symptoms, injection history and progress.

Portal will create and maintain a record of processing in the development stage that will include all data fields collected, the name and contact details of Portal and LEO Pharma and their respective data protection officers, the purposes for which the data is processed, the data subjects from whom such data is obtained, the recipients to whom such data is or will be disclosed, the envisaged time limits for erasure of such data, a description of the physical, technical and organisational security measures to protect such data and, if applicable, a description of any transfer mechanism to be used to export data outside the EEA and the applicable safeguards in place.

What legal basis can our customers (the data controllers) rely on for the processing of Personal Data by the Product Interface?

Each controller will ensure that it has an appropriate basis to process personal data for its respective purposes and, specifically, health data, under Article 6 and Article 9 of the GDPR.

For the commercial phase of the Product Interface, consent can be relied on as a legal basis and can be sought through the Product Interface. The JDC will consult on the consent flow and the mechanism to maintain consent records. The Product Interface shall include functionality to ensure that data subjects can provide consent on a granular purpose-by-purpose basis, including for sharing of personal data with third parties. With the exception of patient registration and warranty details (which are necessary in the event of a recall) consent will not be linked to the use of the Product Interface.

If consent is not practicable for data used in the development phase (e.g. test data) then other legal bases may be available (e.g. Article 6(1)(f) of the GDPR (the processing is necessary for the legitimate interests of the controller) together with Articles 9(2)(i) and/or 9(2)(j) of the GDPR (the processing is necessary for reasons of public interest in the area of public health, such as e.g. ensuring high standards of quality and safety of health care and of medical products or medical devices (Article 9(2)(i) and/or the processing is necessary for scientific research where based on a specific national law in the EU country in question (art. 9(2)(j)) and the parties will consult and agree on the legal bases for processing.

How will individuals be informed about the Personal Data collected and the purpose of the collection?

The Product Interface will be developed to enable Portal and LEO Pharma to provide transparent information in the sign-up flow, which will link to a full privacy policy which must be accepted before use. Portal will provide any necessary information LEO Pharma needs to finalise the information in its privacy policy. The Product Interface shall include functionality to ensure that data subjects are provided with all required information in relation to each party's data processing activities and allows data subjects to consent on a purpose-by-purpose basis where necessary to such data processing, including for sharing of personal data with third parties.

Is Personal Data of individuals shared with third parties?

Each patient may opt-in to the sharing of their personal data with the treating physician, pharmacy or other healthcare provider.

If a patient opts-in to such sharing, Portal will ensure that appropriate agreements are put in place with the relevant parties with whom personal data is shared.

Portal may use sub-processors and will ensure compliance with the GDPR including Article 28, including through vetting and overseeing such sub-processors.

Where will Personal Data be stored?

Data will be stored on Amazon Web Services (AWS) servers in the United States. AWS is certified under the Privacy Shield framework for the transfer of personal data from the EEA.

For how long is Personal Data retained?

The Product Interface will be built to ensure Portal and LEO Pharma can delete personal data once it is no longer than is necessary for the purposes for which it is processed. The retention period in each case will be defined by each party and specified in the privacy notices given to individuals. If data has been irreversibly anonymized in compliance with the GDPR, the parties may retain such anonymized data indefinitely.

How are data subjects' rights managed?

Each party will use appropriate physical, technical and organisational measures in fulfilling their obligation to protect personal data, and shall develop and implement internal compliance infrastructure to receive and respond to requests for exercising data subject's rights, including by implementing and ability to search and access data and to provide data in a portable form. Each party will provide reasonable assistance to the other in responding to requests for exercising data subject's rights. Portal will also enable automated data deletion by LEO Pharma on a [patient record level] basis.

Who can I contact if I have any additional questions on the GDPR and either party's privacy practices?

Portal has appointed a data protection officer who can be contacted at [*details to be inserted*]. LEO Pharma's data protection officer can be contacted at [*details to be inserted*].

How is data secured?

LEO Pharma and Portal will implement appropriate physical, technical and organisational measures to ensure a level of security that meets all relevant legal requirements and is appropriate to the risk to individuals.

LEO Pharma and Portal will maintain disaster recovery protections and protocols consistent with applicable data protection laws and best industry standards.

Each party will notify the other of any suspected security incidents affecting information technology infrastructure housing personal data and/or personal data breach relating to the personal data processed without undue delay on becoming aware (and no later than twenty-four (24) hours of becoming aware of such an incident) and provide any further information reasonably required for the relevant data controller, as applicable, to meet its legal requirements.